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Senate Hearings

Before the Committee on Appropriations

Departments of Labor and Health, Education, and Welfare and Related Agencies Appropriations

Fiscal Year 1980

96*th* CONGRESS, FIRST SESSION

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PART 2—(Pages 1–1081)

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DEPARTMENTS OF LABOR AND HEALTH, EDUCATION, AND WELFARE AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 1980

HEARINGS

BEFORE A

SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS UNITED STATES SENATE

NINETY-SIXTH CONGRESS

FIRST SESSION

PART 2 (Pages 1–1081)

Department of Health, Education, and Welfare
Health Services Administration
Center for Disease Control
National Institutes of Health
Alcohol, Drug Abuse, and Mental Health Administration
Health Resources Administration
Health Care Financing Administration

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DEPARTMENTS OF LABOR AND HEALTH, EDUCATION, AND WELFARE AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 1980

MONDAY, FEBRUARY 26, 1979

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
Washington, D.C.

The subcommittee met at 2:40 p.m. in room S–128, the Capitol, Hon. Warren G. Magnuson (chairman) presiding.

Present: Senators Magnuson, Eagleton, Chiles, Hatfield, Mathias, Schweiker, and Schmitt.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

STATEMENT OF JOSEPH A. CALIFANO, JR., SECRETARY

BUDGET REQUEST

Chairman MAGNUSON. We are here this afternoon to hear from the Secretary of Health, Education, and Welfare, Joseph Califano.

Expenditures for the HEW programs now make up 37.5 percent of the Federal budget. This is the largest share that HEW has ever commanded of the total budget. Even with the budgetcutting that has been planned, HEW still plans to spend $200 billion in fiscal year 1980 for the economically and socially disadvantaged members of our society. Most of this money, however, will come out of the social security trust funds. I have a running argument with the Budget Committee whether or not these funds are to be included in the budget estimates, but they are $117 billion. $15 billion more than last year will be paid to senior citizens and the disabled, as well as to their dependents. This is almost exactly the same amount as is expected to be paid into the trust funds through social security taxes. The input agrees with the output.

Such a major increase in program costs that by law must be paid out allows less money for discretionary social programs. Some say that Secretary Califano has presented us with a responsible, if less than generous, budget request for the HEW funds that must be appropriated. But we will take a look at that. [Laughter.]

The $60.8 billion left being requested is approximately $2.3 billion, or 4 percent, more than the fiscal year 1979 level requested in the President's budget, and $3.7 billion more than we have appropriated so far for fiscal year 1979.

The committee has looked over the budget carefully and, as is ordinarily the case, is not in total agreement with the administration's priorities. For instance, Public Health Service hospitals is one item I want to discuss with the Secretary. Nurse training would no longer be federally supported by your proposed budget. Community mental health programs are proposed in the budget for a $72 million cut.

On the other hand, there is Federal impact aid for education districts with parents who work on Federal property but pay property taxes, and that would, again, be eliminated in this current budget. That is the recommendation for class B students.

The committee has generally agreed that this program is not the most effective way to spend Federal funds. But I believe the ultimate goals of the executive and the legislative branches of Government are identical in the human resources area:

One: To assist those who cannot adequately care for themselves;

Two: To promote the maximum economic and social self-sufficiency that all our citizens are capable of; and to accomplish these goals in the most efficient and cost-effective manner possible. And I underline that last proposal, the most efficient and cost-effective manner possible.

So, Mr. Secretary, it is good to see you here again, and we would be pleased to hear your explanation of this year's budget priorities.

Does anybody else have a statement to make?

Senator SCHMITT. Mr. Chairman, I would say it is good to be here. I was just appointed this morning as a member of the subcommittee.

Chairman MAGNUSON. We want to welcome you as a new member, and all the other new members that show up here at these hearings.

Senator SCHMITT. You may find out we disagree a little bit on the impact aid, depending upon the economic viability.

Chairman MAGNUSON. We are always willing to have help, wherever it comes from, from the executive departments or from the committee. But this is a very, very important item in the budget, and it involves the question we have all been reading about, of balancing the budget and what are the priorities of all these things.

So we are going to have a heavy schedule here, and we are going to look at these matters as best we can.

Senator SCHMITT. Mr. Chairman, also, I hope—and I'm sure that the Secretary will assist us in examining those areas of his budget where, through his efforts and other efforts, there have been well-documented problems with fraud and abuse and where we can avoid cutting programs that I think many people would say are necessary, and concentrate on improving the administration of those programs, and that is by far the best way to have a lean and austere budget.

I know the Secretary has been working very hard on this, and I hope that the committee can also begin to dig into that.

Chairman MAGNUSON. I would say to you that we have been working on this for many, many years around here, and sometimes we accomplish it and sometimes we don't. But we are all in agreement on the question of more efficient operation of Government and the question of fraud and abuse and things that big budgets such as this are susceptible to.

All right, Mr. Secretary.
[The statement follows:]

STATEMENT OF JOSEPH A. CALIFANO, JR.

IT IS A PLEASURE TO APPEAR BEFORE YOU TODAY TO PRESENT THE DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE'S 1980 BUDGET.

IN A YEAR WHEN INFLATION ONCE AGAIN THREATENS THE QUALITY OF ALL OUR LIVES, THE NECESSITY FOR FISCAL RESTRAINT CANNOT BE DENIED. BUT FISCAL RESTRAINT MUST NOT SERVE AS AN EXCUSE FOR IGNORING THOSE LEAST ABLE TO HELP THEMSELVES. THIS HAS BEEN A DIFFICULT BUDGET, BUT I BELIEVE IT CHARTS A REASONABLE COURSE BETWEEN THE NEED FOR RESTRAINT ON THE ONE HAND AND THE NEEDS OF THOSE WHO DEPEND ON OUR SERVICES MOST--THE MOST VULNERABLE PEOPLE IN THIS NATION--THE POOR, THE AGED, THE SICK, THE HANDICAPPED, AND THE YOUNG.

THE HEW BUDGET ATTEMPTS TO DISCIPLINE RUNAWAY COSTS AND ELIMINATE WASTE TO FUND HIGH PRIORITY PROGRAMS. BECAUSE OF OUR EFFORTS TO CONTAIN COSTS--PARTICULARLY NEW LEGISLATION CONTROLLING ENTITLEMENT SPENDING--HEW'S 1980 BUDGET IS $2.4 BILLION UNDER CURRENT SERVICES. OUR 1980 PROPOSALS BUILD ON THE ACCOMPLISHMENTS OF THE FIRST TWO YEARS OF THE CARTER ADMINISTRATION. OUR BUDGET AND LEGISLATIVE PROPOSALS EMPHASIZE:

- PROGRAMS WHICH EXTEND OR STRENGTHEN SERVICES FOR THE POOR AND UNDERSERVED;
- PROGRAMS WHICH REDIRECT PUBLIC HEALTH SPENDING TO PLACE GREATER EMPHASIS ON PREVENTION, MENTAL HEALTH, AND REFORMS OF THE HEALTH CARE SYSTEM;

- o Reforms of entitlement programs to strengthen the basic protection these programs provide while saving Federal outlays in FY 1980 and future years.
- o Management improvements to make HEW resources more productive and free funds for new initiatives.

Before discussing our most significant proposals, I would like to put the fiscal 1980 budget in a broader context.

First, the fiscal 1980 HEW budget must be seen from a national perspective.

Federal budget restraint is a necessary part of an overall strategy to deal with the inflation that afflicts moderate and low-income citizens alike and that erodes our Nation's will--and its ability--to marshal the resources necessary to deal with the unfinished domestic agenda. Congress and the President must work toward the common goal of holding the 1980 budget deficit under $30 billion.

Having participated with the President in the preparation of this budget, I think it is important that this committee, and the American people, know that he is deeply concerned about the social needs of our citizens. He has given them careful and compassionate consideration in formulating a budget that necessarily must slow the growth in government spending.

Second, the fiscal 1980 HEW budget must be seen in historical perspective; it sustains the nation's commitment to meet social needs that was initially forged during the Kennedy-Johnson years.

- In 1963, the HEW budget was $20.7 billion or 18.6 percent of the Federal budget. Under President Carter's proposed fiscal 1980 budget, the HEW budget will be $199.4 billion or 37.5 percent of the Federal budget. By contrast, the budget for the Department of Defense, which was $47.9 billion or 44 percent of the Federal budget in 1963, will be $125 billion or 23.6 percent of the Federal budget in 1980. Thus, in 17 years, the HEW budget has more than doubled its share of total Federal spending, while DOD's budget share has dropped sharply.

- In 1980, the President has allocated half of the total Federal budget increase to HEW. The total budget grows by $38.2 billion, of which $18.7 billion is for HEW.

Thus, reductions in specific HEW programs must be seen against the backdrop of overall increases in total HEW spending. Moreover, many of the reductions, such as those from Hospital Cost Containment and other management and efficiency initiatives in AFDC and Medicaid, save money for State and local governments as well as the Federal

BUDGET. IF PROPERLY IMPLEMENTED BY HEW AND SERVICE PROVIDERS, THESE COST-SAVINGS PROPOSALS SHOULD NOT LEAD TO ANY REDUCTION IN THE QUANTITY OR QUALITY OF NECESSARY SERVICES FOR HEW BENEFICIARIES.

I WOULD MAKE ONE OTHER OBSERVATION ABOUT THE INCREASE IN THE HEW BUDGET. MUCH OF IT, IN RECENT YEARS, IS A RESULT OF INFLATION ADJUSTMENTS IN THE ENTITLEMENT PROGRAMS--SOCIAL SECURITY, MEDICARE AND MEDICAID. INDEED, ENTITLEMENT PROGRAMS TODAY ACCOUNT FOR ALMOST $9 OF EVERY $10 SPENT BY THE DEPARTMENT.

INFLATION IS RAVAGING THE DOLLARS AVAILABLE FOR THE DEPARTMENT'S DISCRETIONARY PROGRAMS IN EDUCATION, HEALTH AND SOCIAL SERVICE. FOCUS FOR A MOMENT ON THIS STARTLING FACT: FOR EVERY 1% OF INFLATION, SPENDING FOR HEW'S ENTITLEMENT PROGRAMS AUTOMATICALLY INCREASES MORE THAN $1.4 BILLION. TO THE EXTENT THAT WE CAN CONTROL INFLATION AND REDUCE AUTOMATIC INCREASES IN THE ENTITLEMENT PROGRAMS, WE CAN UNLOCK ADDITIONAL PRECIOUS RESOURCES FOR IMPORTANT NEW PROGRAM INITIATIVES AND REAL EXPANSION OF SERVICES.

Budget Savings

BECAUSE OF INFLATIONARY PRESSURES, THE INEXORABLE GROWTH OF ENTITLEMENT PROGRAMS, AND OUR SHARED COMMITMENT TO REDUCE FRAUD AND WASTE TO THE ABSOLUTE MINIMUM, THE 1980 BUDGET REFLECTS AN INTENSE EFFORT TO REDUCE OUTLAYS AND AVOID UNNECESSARY COSTS.

THIS EFFORT IS ESSENTIAL IF WE ARE TO FREE UP THE RESOURCES NEEDED FOR THE NEW INITIATIVES PROPOSED IN THIS BUDGET. IN THE AGGREGATE, ACTIONS UNDERTAKEN DURING OUR FIRST TWO YEARS

IN OFFICE AND NEW PROPOSALS PUT FORWARD IN THE 1980 BUDGET WILL SAVE $1.6 BILLION IN 1979 AND $5.8 BILLION IN 1980.

A LARGE PART OF THESE SAVINGS REQUIRE ACTION BY CONGRESS EITHER TO MODIFY THE LAWS AUTHORIZING ENTITLEMENT PROGRAMS OR TO APPROVE LOWER SPENDING LEVELS THROUGH THE APPROPRIATIONS PROCESS. OVERALL, $3.4 BILLION OF OUR PROPOSED 1980 SAVINGS REQUIRE ACTION BY CONGRESS. I STRONGLY URGE THAT YOUR COMMITTEE ENDORSE THESE PROPOSALS INCLUDING THE APPROPRIATE PARTS IN YOUR APPROPRIATION BILLS AND ENCOURAGE THE AUTHORIZING COMMITTEES TO TAKE SIMILAR ACTIONS TO ENSURE THAT RESOURCES WILL BE AVAILABLE FOR OUR IMPORTANT NEW INITIATIVES.

ADMINISTRATIVE ACTIONS WE HAVE TAKEN AND PROPOSE TO TAKE DURING THE NEXT YEAR AND A HALF WILL SAVE $1.2 BILLION IN 1979 AND $2.4 BILLION IN 1980. THESE INCLUDE BOTH REVISIONS IN REGULATIONS GOVERNING ENTITLEMENT PROGRAMS AND ADMINISTRATIVE ACTIONS TO REDUCE FRAUD AND WASTE. WE ALSO ASK YOUR SUPPORT TO ACHIEVE THESE ADMINISTRATIVE SAVINGS.

LABOR-HEW APPROPRIATIONS BILL

UP TO NOW, I HAVE DISCUSSED HEW'S TOTAL BUDGET INCLUDING OUTLAYS FROM TRUST FUNDS AS WELL AS THE APPROPRIATION REQUESTS CONSIDERED BY THE LABOR-HEW APPROPRIATIONS SUBCOMMITTEE. FOR FISCAL YEAR 1980, WE ARE ASKING YOU TO RECOMMEND AN HEW APPROPRIATION OF $61.2 BILLION, INCLUDING APPROPRIATIONS FOR NEW LEGISLATION PROPOSED WITH THIS BUDGET. THIS IS AN INCREASE

OF $2.8 BILLION OVER OUR CURRENT REQUEST FOR 1979, PRIMARILY BECAUSE OF INCREASED REQUIREMENTS IN THE ENTITLEMENT PROGRAMS. ALTHOUGH FUNDING FOR DISCRETIONARY PROGRAMS STAYS AT ROUGHLY THE 1979 LEVEL, WE ARE RECOMMENDING SELECTED REDUCTIONS TO FUND NEW INITIATIVES IN HIGH PRIORITY AREAS.

NEW LEGISLATION IN THE 1980 BUDGET INCLUDES COST SAVINGS LEGISLATION IN MEDICAID AND AFDC, A PERMANENT $2.9 BILLION TITLE XX CEILING, AND NEW INITIATIVES IN MENTAL HEALTH AND CHILD WELFARE, AND AN EXPANDED CHILD HEALTH ASSURANCE PROGRAM UNDER MEDICAID.

HEW'S CURRENT REQUEST FOR 1979 INCLUDES $1.6 BILLION IN SUPPLEMENTALS AND $227 MILLION IN APPROPRIATION RESCISSIONS THAT WE ARE ASKING YOU TO APPROVE. ABOUT ONE-HALF OF THE SUPPLEMENTAL REQUESTS ARE FOR HIGHER ENTITLEMENT APPROPRIATIONS (MAINLY IN THE MEDICAID AND GUARANTEED STUDENT LOAN PROGRAMS). THE REMAINING SUPPLEMENTAL REQUESTS IMPLEMENT LEGISLATIVE AUTHORITIES ENACTED IN THE LAST SESSION OF CONGRESS--COMMUNITY HEALTH, HMO'S, TITLE I ESEA, TITLE XX SOCIAL SERVICES, HEAD START AND REHABILITATION SERVICES.

HEALTH PROGRAMS

THE HEALTH BUDGET SEEKS TO CONTAIN COSTS AND FOCUS DISCRETIONARY FEDERAL HEALTH RESOURCES ON ACTIVITIES THAT PREVENT ILLNESS AND PROMOTE WELL-BEING, ENCOURAGE MORE EFFECTIVE MENTAL HEALTH SERVICES, AND REFORM THE HEALTH DELIVERY SYSTEM.

THE 1980 BUDGET PROPOSES $56.3 BILLION IN BUDGET AUTHORITY FOR THE DEPARTMENT'S HEALTH PROGRAMS, $5 BILLION

MORE THAN OUR CURRENT ESTIMATE FOR 1979. THE MAJOR FACTOR IN THIS INCREASE IS RISING INCOME TO THE MEDICARE TRUST FUNDS FROM SOCIAL SECURITY TAXES AND PREMIUMS FROM ENROLLED BENEFICIARIES. THE TOTAL HEALTH BUDGET INCLUDES $7.8 BILLION IN NEW BUDGET AUTHORITY FOR THE PUBLIC HEALTH SERVICE; $12.7 BILLION FOR MEDICAID AND RELATED ACTIVITIES REQUIRING APPROPRIATIONS ACTION; AND $35.8 BILLION FOR THE MEDICARE TRUST FUNDS, NOT UNDER THE DIRECT JURISDICTION OF THIS COMMITTEE.

MAJOR EFFORTS TO CONTAIN HEALTH COSTS

OUR FY 1980 BUDGET ANTICIPATES OVERALL SAVINGS OF $3.3 BILLION IN HEALTH CARE PROGRAMS. THIS INCLUDES PROPOSED NEW LEGISLATION AND ADMINISTRATIVE ACTIONS THAT WE BEGAN IN FISCAL YEAR 1978 AND ARE INTENSIFYING AND STRENGTHENING IN 1979 AND 1980. ALTHOUGH THESE PROPOSALS DO NOT REQUIRE IMMEDIATE ACTION BY THE APPROPRIATIONS COMMITTEE, I WILL SUMMARIZE THE MAJOR ONES BECAUSE OF THEIR IMPORTANCE TO THE TOTAL BUDGET.

-- HOSPITAL COST CONTAINMENT. OUR MOST SIGNIFICANT COST SAVINGS PROPOSAL IS THE CONTAINMENT OF RUNAWAY HOSPITAL COSTS. AS YOU ARE AWARE, DURING THE PAST TWO YEARS THE ADMINISTRATION HAS SOUGHT TO CONSTRAIN THE RAPID RISE IN HOSPITAL COSTS THROUGH PASSAGE OF HOSPITAL COST CONTAINMENT LEGISLATION. HOSPITAL SERVICES ARE THE MOST EXPENSIVE COMPONENT OF THE HEALTH CARE INDUSTRY--ACCOUNTING FOR 40 PERCENT OF ALL HEALTH COSTS.

THE PRESIDENT WILL SUBMIT A NEW PROPOSAL TO LIMIT THE GROWTH IN HOSPITAL EXPENDITURES. BASED ON THE ADMINISTRATION'S ANTI-INFLATION GUIDELINE, ANNOUNCED LAST DECEMBER, THE BUDGET PROJECTS A SAVINGS OF $1.7 BILLION IN 1980 IN FEDERAL HEALTH CARE COSTS AND $4.4 BILLION FOR ALL PAYORS.

-- RESTRUCTURED MEDICARE COVERAGE FOR THE WORKING AGED. WE WILL PROPOSE LEGISLATION THAT WILL REQUIRE PRIVATE EMPLOYERS TO CONTRIBUTE TO THE COST OF HOSPITAL INSURANCE FOR ALL WORKERS WHO ARE ABOVE THE AGE OF 65. WE ESTIMATE THAT THIS PROPOSAL WILL SAVE $200 MILLION IN THE MEDICARE TRUST FUNDS.

-- TIGHTENED REIMBURSEMENT REGULATIONS. OUR PRINCIPAL NEW PROPOSAL IS TO REIMBURSE HOSPITALS FOR MALPRACTICE INSURANCE COSTS PROPORTIONAL TO ACTUAL CLAIMS MADE BY FEDERAL BENEFICIARIES, A $310 MILLION SAVINGS.

-- WE ALSO PLAN TO REVISE THE REIMBURSEMENT GUIDELINES UNDER SECTION 223 OF THE SOCIAL SECURITY ACT TO EXTEND REIMBURSEMENT LIMITS FOR INEFFICIENT PROVIDERS TO NURSING HOMES AND HOME HEALTH AGENCIES AS WELL AS HOSPITALS. THIS PROPOSAL WILL SAVE $105 MILLION IN 1980.

-- EFFORTS TO CONTROL FRAUD AND ABUSE. WE HAVE BEGUN A NUMBER OF ADMINISTRATIVE EFFORTS TO ELIMINATE IMPROPER MEDICARE AND MEDICAID REIMBURSEMENTS

WHICH WILL SAVE AN ESTIMATED $725 MILLION IN 1980. OUR LARGEST EFFORT, THE MEDICAID QUALITY CONTROL PROGRAM, SEEKS TO REDUCE THE OVERALL MEDICAID ERROR RATE BY 1 PERCENT A YEAR STARTING IN FISCAL YEAR 1979.

CHILD HEALTH (CHAP) INITIATIVE

WE ARE PROPOSING $288 MILLION FOR A REVISED CHILD HEALTH ASSURANCE PROGRAM (CHAP), WHICH WE FIRST RECOMMENDED TO THE 95TH CONGRESS. OUR OBJECTIVE IS TO ASSURE THAT NEEDY CHILDREN RECEIVE COMPREHENSIVE, RATHER THAN PIECEMEAL HEALTH CARE. THE CHAP LEGISLATION WILL EXTEND MEDICAID ELIGIBILITY TO AN ADDITIONAL TWO MILLION POOR CHILDREN AND 100,000 LOW-INCOME PREGNANT WOMEN. IT WILL ALSO EXTEND DENTAL, VISION, HEARING, AND OUT-PATIENT MENTAL HEALTH BENEFITS TO ALL MEDICAID CHILDREN, AND ENCOURAGE PROVIDERS TO DELIVER COMPREHENSIVE AMBULATORY SERVICES TO MEDICAID CHILDREN ON A CONTINUING BASIS.

THE FUNDS TO CARRY OUT THIS NEW PROGRAM WILL BE REQUESTED FROM THE CONGRESS AS SOON AS THE NEW LEGISLATION IS ENACTED.

PUBLIC HEALTH SERVICE

THREE MAJOR HEALTH INITIATIVES ARE BEING PROPOSED WITHIN THE $7.8 BILLION PHS BUDGET FOR 1980 OF WHICH $6.9 BILLION WILL BE CONSIDERED BY YOUR SUBCOMMITTEE.

FOR NEW EFFORTS IN MENTAL HEALTH AND ALCOHOLISM, THE FY 1980 BUDGET PROVIDES $1.2 BILLION, A NET INCREASE OF $91 MILLION, WHICH WILL SUPPORT NEW OR EXPANDED PROGRAMS TO:

- PROVIDE MORE FLEXIBLE FUNDING FOR COMMUNITY-BASED MENTAL HEALTH SERVICES AND TARGET

THOSE SERVICES ON THE NEEDIEST POPULATIONS. A CONSOLIDATED GRANT WOULD REPLACE THE EXISTING STATE FORMULA GRANT PROGRAMS.

- o STRENGTHEN STATE MENTAL HEALTH PROGRAMS TO IMPROVE SERVICES, ESPECIALLY FOR THOSE WITH CHRONIC MENTAL ILLNESS AND SEVERELY DISTURBED CHILDREN AND YOUTH.

- o TARGET NEW ALCOHOLISM SERVICE PROGRAMS ON HIGH-RISK POPULATIONS, ESPECIALLY WOMEN AND YOUTH.

THE FY 1980 BUDGET ALSO INCLUDES A NET INCREASE OF $137 MILLION TO LAUNCH AND STRENGTHEN EFFORTS IN PREVENTIVE HEALTH. THESE EFFORTS WILL:

- o CALL SPECIAL ATTENTION TO HEALTH PROBLEMS--PARTICULARLY FOR WOMEN AND CHILDREN--CAUSED BY SMOKING AND INADEQUATE NUTRITION, INCLUDING EXPENDITURES IN FISCAL 1980 OF $47.2 MILLION FOR RESEARCH, EDUCATION, AND PREVENTION ACTIVITIES RELATED TO SMOKING AND HEALTH;

- o INCREASE INFORMATION AND AWARENESS AMONG CHILDREN, AS WELL AS ADULTS, OF RISKS TO GOOD HEALTH--THROUGH PROGRAMS CONDUCTED IN SCHOOLS AND PRE-SCHOOL LOCATIONS, THE WORKSITE, THE COMMUNITY AND HEALTH FACILITIES;

- o EXPAND SCREENING AND SERVICE PROGRAMS TARGETED AT IDENTIFIABLE DISEASES-- SUCH AS HYPERTENSION--AND VULNERABLE POPULATION GROUPS;

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- o Encourage communities to fluoridate their water supply and make an increased effort to prevent hospital-related infections. $6.2 million will be spent for new fluoridation activity, serving over 3 million more people.

Funding for childhood immunization can be decreased by $16.5 million because of our success in immunizing the "backlog" of previously unprotected children against measles, polio, rubella and other childhood diseases:

-- By the end of this year, we expect that 90 percent of all children will be protected;

-- We expect that nearly 100% of all school age children will have been immunized;

-- 3.6 million additional children will be immunized with funds requested in 1980, the appropriate "maintenance" level.

The ongoing influenza immunization program will also be continued in 1980, serving an estimated 14 million people.

Another initiative in fiscal 1980 will be in the area of <u>adolescent health services</u>. As part of our overall health strategy, we are requesting a supplemental of $7 million in 1979 and an appropriation of $60 million in fiscal 1980 to implement the newly enacted teenage pregnancy program contained in the Health Services and Centers Amendments of 1978. Under this new program, health and support services will be

PROVIDED TO MORE THAN 78,000 ADOLESCENTS, INCLUDING PRENATAL AND OBSTETRICAL CARE FOR THE PREGNANT TEENAGER WHO DECIDES TO HAVE HER BABY, AND FOR PREVENTING SUBSEQUENT ADOLESCENT PREGNANCIES.

THE FISCAL 1980 BUDGET ALSO CONTAINS ADDITIONAL FUNDS FOR NEEDED REFORMS OF THE HEALTH CARE SERVICE AND DELIVERY SYSTEM. BECAUSE HEALTH MAINTENANCE ORGANIZATIONS HAVE PROVEN TO BE A MORE EFFICIENT METHOD OF HEALTH CARE DELIVERY, WE PROPOSE FUNDING BOTH TO INCREASE THE NUMBER OF PROJECTS AND TO EXPAND COVERAGE OF EXISTING HMO GRANTEES. WE ARE REQUESTING $74 MILLION FOR THE HMO PROGRAM, NEARLY DOUBLE OUR 1979 BUDGET, AND THE LARGEST ANNUAL INCREASE IN THE HISTORY OF THE PROGRAM.

IN ORDER TO MEET THE NEEDS OF MEDICALLY UNDERSERVED AREAS WE PROPOSE TO EXPAND THE NATIONAL HEALTH SERVICE CORPS BY PLACING 1,100 MORE HEALTH PROFESSIONALS IN UNDERSERVED AREAS IN 1980--A 63 PERCENT INCREASE OVER THE CURRENT LEVEL.

AND, WE WILL INCREASE THE COMMUNITY HEALTH CENTER PROGRAM BY $81 MILLION IN 1979 AND $30 MILLION IN 1980, TO ENABLE A TOTAL OF 890 COMMUNITY HEALTH PROJECTS TO SERVE AN ADDITIONAL ONE MILLION NEEDY PATIENTS A YEAR. OF THESE, 80 WILL BE NEW RURAL HEALTH CENTERS AND 54 NEW INNER CITY HEALTH PROJECTS.

OFFSETS IN PHS PROGRAMS

IN ORDER TO SUPPORT INITIATIVES IN FISCAL 1980 FOR PRIORITY CONCERNS WITHIN THE OVERALL BUDGET CONSTRAINTS, WE HAVE HAD TO MAKE SOME DIFFICULT DECISIONS. THERE ARE SOME PROGRAMS IN THE HEALTH BUDGET THAT WILL BE LEVEL FUNDED IN 1980; THERE ARE OTHER PROGRAMS WHERE WE HAVE RECOMMENDED REDUCED, OR EVEN ELIMINATION OF FEDERAL FUNDING.

THE ADMINISTRATION IS PROPOSING OVERALL REDUCTIONS IN HEALTH MANPOWER PROGRAMS. THE LARGEST REDUCTION IS THE ELIMINATION OF CAPITATION GRANTS FOR HEALTH PROFESSIONS SCHOOLS. THE CAPITATION GRANT PROGRAM IS NOT SUFFICIENTLY TARGETED TO MEET THE NATION'S MOST PRESSING HEALTH MANPOWER NEEDS. AS A PARTIAL OFFSET TO THIS PROPOSED REDUCTION, THE BUDGET DOES PROVIDE FOR INCREASED RESOURCES TO TRAIN MORE PRIMARY CARE PRACTITIONERS, AND OTHER HEALTH PROFESSIONALS NOW IN SHORT SUPPLY. BUT IT IS IMPORTANT TO TAKE STEPS TO REDUCE FEDERAL SUPPORT FOR EDUCATION IN THOSE HEALTH PROFESSIONS WHERE THERE ALREADY EXIST AN ADEQUATE--OR IN SOME CASES AN OVER-ABUNDANT--SUPPLY.

WITH RESPECT TO NURSING, THE ADMINISTRATION IS REDUCING FUNDS FOR INSTITUTIONAL SUPPORT AND STUDENT ASSISTANCE BECAUSE THE EXPERTS, INCLUDING CBO, ESTIMATE THAT THE TOTAL SUPPLY OF NURSES WILL MEET OR EXCEED DEMAND OVER THE NEXT DECADE WITHOUT CONTINUING FEDERAL ASSISTANCE. TO THE EXTENT THAT STUDENTS REQUIRE FINANCIAL AID FOR NURSING EDUCATION, THEY WILL BE ABLE TO USE GENERAL FEDERAL

STUDENT ASSISTANCE PROGRAMS--SUCH AS BASIC EDUCATIONAL OPPORTUNITY GRANTS OR FEDERAL LOAN PROGRAMS. WE WILL CONTINUE TO FUND SPECIAL PROJECTS TO IMPROVE NURSING FOR UNDERSERVED TARGET GROUPS--ESPECIALLY THE ELDERLY AND CHILDREN. WE WILL ALSO CONTINUE TO INCREASE THE SUPPLY OF NURSE PRACTITIONERS WHO PROVIDE PRIMARY CARE IN BOTH THE FORMAL HEALTH CARE DELIVERY SETTING AND ELSEWHERE.

THE FISCAL 1980 BUDGET PROPOSES ESSENTIALLY LEVEL FUNDING FOR NIH RESEARCH. OVER THE LAST TEN YEARS, NIH HAS RECEIVED A VERY GENEROUS SHARE OF THE INCREASE IN THE FEDERAL HEALTH BUDGET. IN 1978 AND 1979, FOR EXAMPLE, THE NIH RESEARCH BUDGET INCREASED BY 12 PERCENT AND 14 PERCENT RESPECTIVELY. BETWEEN FY 1969 AND FY 1979, THE NIH BUDGET ROSE FROM $1.1 BILLION TO $3.2 BILLION, A 190% INCREASE--MEASURED IN CONSTANT DOLLARS, NIH HAS GROWN BY 50% DURING THIS SAME PERIOD.

EDUCATION DIVISION

THE EDUCATION BUDGET FOR 1980 BUILDS ON TWO MAJOR PIECES OF LEGISLATION REQUESTED BY THIS ADMINISTRATION AND PASSED BY THE CONGRESS IN 1978. THE EDUCATION AMENDMENTS OF 1978 AUTHORIZED AN EXPANDED PROGRAM OF ELEMENTARY AND SECONDARY EDUCATION; AND THE MIDDLE-INCOME STUDENT ASSISTANCE ACT IMPROVED ACCESS TO HIGHER EDUCATION FOR MORE THAN ONE MILLION STUDENTS FROM MIDDLE-INCOME FAMILIES.

In total we are requesting $12.2 billion in budget authority for the Education Division, $390 million less than current appropriations and recommended supplementals for 1979. This reduction is primarily the result of (1) a lower estimate of the cost of implementing the Middle Income Student Assistance initiative and, (2) a shift in resources from general support programs such as Impact Aid and Direct Student Loans to programs aiding the disadvantaged, such as Title I of the Elementary and Secondary Education Act and Education for the Handicapped.

Elementary and Secondary Education

The 1980 request for Elementary and Secondary education programs emphasizes assistance for needy students and improved teaching of basic skills. The budget increases funding for programs supporting these objectives by $228 million--from $5.2 billion in 1979 to $5.4 billion in 1980.

- HEW is proposing $658 million over two years for the concentration provision of Title I of the Elementary and Secondary Education Act. This cornerstone of the Administration's 1978 elementary and secondary legislative proposals targets Title I funds on the neediest school districts to help meet the special needs of educationally disadvantaged children.

  The 1980 budget meets the Administration's commitment to seek $400 million for this new provision and includes a proposed supplemental of $258 million to initiate the program in 1979. The new concentration

PROVISION COULD SERVE AN ADDITIONAL 850,000 TO 900,000 DISADVANTAGED STUDENTS BY 1980 AT A PER PUPIL EXPENDITURE RANGING FROM $435 TO $460.

HEW PROPOSES TO CONTINUE THE REGULAR TITLE I PROGRAM AT THE 1979 LEVEL OF $3 BILLION. ABOUT 5.7 TO 6 MILLION STUDENTS IN LOCAL SCHOOL DISTRICTS WILL CONTINUE TO RECEIVE SERVICES.

- THE 1980 BUDGET PROPOSES $1 BILLION FOR EDUCATION OF THE HANDICAPPED. TO HELP STATES MEET THEIR RESPONSIBILITY TO EDUCATE HANDICAPPED CHILDREN, THE ADMINISTRATION PROPOSES TO CONTINUE ITS 1979 POLICY OF PROVIDING EXTRA FUNDS EQUAL TO 12 PERCENT OF THE NATIONAL AVERAGE PER PUPIL EXPENDITURE. TO CARRY OUT THIS POLICY, THE BUDGET INCLUDES $862 MILLION FOR THE STATE GRANT PROGRAM IN 1980, AN INCREASE OF $58 MILLION. THESE FUNDS WILL BE USED DURING THE 1980-81 SCHOOL YEAR TO SERVE NEARLY 4 MILLION CHILDREN.

- THE BUDGET PROPOSES AN INCREASE OF $22 MILLION FOR DESEGREGATION ASSISTANCE, EXPANDING THE ADMINISTRATION'S COMMITMENT TO SCHOOL DISTRICTS TRYING TO OVERCOME PROBLEMS OF SCHOOL DESEGREGATION.

  BECAUSE OF CHANGES IN THE EMERGENCY SCHOOL AID ACT, WE WILL BE ABLE FOCUS $40 MILLION IN NEW PROJECTS ON SCHOOL DISTRICTS WITH THE MOST CRITICAL PROBLEMS--$26.5 MILLION FOR NEW PROGRAMS AND PROJECTS FOR SCHOOL DISTRICTS WITH EMERGENCY OR SPECIAL NEEDS; $10 MILLION TO BE AVAILABLE FOR INNOVATIVE DESEGREGATION ACTIVITIES SUCH AS MAGNET SCHOOLS; AND $3.5 MILLION TO BE USED TO SUPPORT SPECIAL EDUCATIONAL TELEVISION AND RADIO PROGRAMS.

We also plan a $16 million expansion for desegregation technical assistance and training activities authorized under Title IV of the Civil Rights Act. These funds provide the greatest flexibility in assistance to local school districts seeking to desegregate.

- The budget includes a $15 million increase for Bilingual Education, or nearly a 10% increase above the 1979 appropriation. The Bilingual Education program will reach 340,000 children in 1980--18,000 more than in 1979--with highest priority directed to activities which help non-English speaking children function in the regular classroom as quickly as possible.

- The budget places new emphasis on Basic Skills and Achievement Testing, one of the highest Federal education priorities. New provisions in the 1978 Education Amendments offer an opportunity to make real gains toward meeting President Carter's goal that all American children be taught to read by the fourth grade.

The 1980 budget provides $35 million for the new Basic Skills Improvement program, an increase of $7 million over its more narrowly focused predecessor--the Right to Read program. The budget also includes $2 million to initiate the new experimental Achievement Testing program, which gives States the opportunity to try out alternative approaches to measuring academic performance. These activities will be further complemented through increased emphasis by the National Institute of Education on research activities dealing with literacy in basic skills.

- The budget expands support for Alcohol, Drug Abuse and School Health Education programs. In order to help parents and educators deal with the growing problem of alcohol and drug abuse among young people, the budget expands support for the Alcohol and Drug Abuse Education program to $3 million. Funds are used primarily to support alcohol and drug abuse education leadership training at the State and local level. The Special Projects appropriation includes $2 million to improve the health of elementary and secondary children through the establishment of school health programs and services. Emphasis will be on activities to discourage smoking among young people.

- The budget proposes full implementation of the Middle Income Student Assistance Act. We are proposing to award up to the statutory maximum of $1,800 to all students eligible for Basic Educational Opportunity Grants. We also propose to implement the new BEOG provisions which treat independent students more like separate family units.

  The lower budget authority requested for BEOGs is a projection from our recent experience which shows the results of our efforts to crosscheck grant applications with other data on family income and resources. If the estimate of participation turns out to be too low, we will propose an appropriate amendment to the budget request to carry out the President's policy of fully funding the BEOG program.

Because of amendments to the Guaranteed Student Loan program which removed all limitations on family income in determining eligibility for Federal subsidies, we expect to guarantee loans for 130,000 more students during the 1977-78 academic year.

- o The budget maintains the current level for Supplemental Grants, Work-Study and Incentive Grants. The budget maintains the 1979 level of $340 million for Supplemental Opportunity Grants, $550 million for College Work-Study, and $77 million for Incentive Grants for State Scholarships. About 573,000 students will receive Supplemental Grant awards averaging $570. Nearly 1 million students will be provided part-time employment during the 1980-81 school year under the Work Study program. And more than 300,000 students will participate in the State incentive grant program.

- o The budget expands graduate and professional opportunities for minorities by providing an increase of $7 million above 1979 for qualified minorities and women under the Graduate/Professional Opportunities program. Funds will be used for fellowships to some 1,700 students pursuing academic and professional careers in fields such as engineering and business in which they have been traditionally underrepresented, double the number of students participating in 1979. We are also requesting $3 million to begin a newly authorized program to attract disadvantaged high school students to pursue careers in biomedical sciences.

- o The budget continues to support developing institutions and TRIO programs serving disadvantaged students. The budget maintains the current maximum authorization of $120 million to aid predominantly black colleges and universities and other institutions enrolling significant percentages of minority students and students from low-income families. In 1980, some 300 institutions will receive grants to improve their administration, faculty, student services, and curriculum. The budget includes $130 million for the TRIO programs: Talent Search, Upward Bound, Special Services and for Educational Opportunity Centers. About 495,000 students will participate in 1980.

Education Offsets

We are proposing two major offsets in Education programs in order to finance priorities:

- o A reduction of $291 million in Impact Aid Maintenance and Operations. We are proposing to eliminate Impact Aid payments for children whose parents work but do not live on Federal property ("B" children). We believe that continued Federal support cannot be justified for "B" children, whose parents pay local taxes to help support the schools, during a period of budget austerity.

- o Savings in Direct Student Loans resulting from increased collections. The 1980 budget proposes $220 million for Federal capital contributions for the Direct Student Loan program, a reduction of $94 million below the current appropriation. This proposed reduction will not lower funds available for loans if participating schools do a better job of collecting defaulted loans. Vigorous

ACTION BY THE OFFICE OF EDUCATION AND THE SCHOOLS CAN RAISE COLLECTIONS TO $412 MILLION, COMPARED TO ABOUT $317 MILLION IN 1979. THESE FUNDS WILL BE RETURNED TO INSTITUTIONAL REVOLVING FUNDS TO SUPPLEMENT THE FEDERAL CAPITAL CONTRIBUTIONS.

HUMAN DEVELOPMENT SERVICES

FOR PROGRAMS ADMINISTERED BY THE OFFICE OF HUMAN DEVELOPMENT SERVICES, WE ARE REQUESTING $5.9 BILLION FOR FISCAL YEAR 1980, INCLUDING $434 MILLION BASED UPON THE ENACTMENT OF NEW LEGISLATION ESTABLISHING A PERMANENT TITLE XX CEILING AT $2.9 BILLION AND THE REFORM OF THE CHILD WELFARE SERVICES PROGRAM.

WE ARE ALSO REQUESTING THE APPROPRIATION OF $321 MILLION IN 1979 SUPPLEMENTALS CARRYING OUT LEGISLATION ENACTED LAST FALL FOR NEW AGING, REHABILITATION, HEAD START AND TITLE XX SOCIAL SERVICE AUTHORIZATIONS.

OVERALL, FUNDING FOR THE HUMAN DEVELOPMENT SERVICES PROGRAMS IS UP $150 MILLION OVER 1979 AND $450 MILLION OVER 1978. FUNDING INCREASES ARE FOCUSED ON SERVICES TO THE POOR AND DISADVANTAGED. IN ADDITION, SOME REDUCTIONS IN NON-SERVICE RESEARCH AND TRAINING ACTIVITIES ARE PROPOSED IN ORDER TO PROVIDE ADDITIONAL RESOURCES FOR DIRECT SERVICE PROGRAMS. HIGHLIGHTS OF THE 1980 HUMAN DEVELOPMENT SERVICES BUDGET INCLUDE THESE MAJOR INITIATIVES.

- $2.9 BILLION PERMANENT CEILING FOR TITLE XX SOCIAL SERVICES. IN THE LAST SESSION, CONGRESS ENACTED A ONE-YEAR INCREASE IN THE TITLE XX PROGRAM FROM $2.5 TO $2.7 BILLION AND CONTINUED FOR ONE ADDITIONAL YEAR THE SEPARATE $200 MILLION DAY CARE PROGRAM. IN 1980, WE ARE SUBMITTING

LEGISLATION TO RAISE THE PERMANENT TITLE XX CEILING TO $2.9 BILLION AND THE SEPARATE DAY CARE PROGRAM WOULD BE FOLDED INTO THE BASIC CEILING, PROVIDING THE STATES WITH THE FLEXIBILITY TO DETERMINE PROGRAM ALLOCATIONS.

WE ARE ALSO REQUESTING A SEPARATE TITLE XX CEILING FOR GUAM, PUERTO RICO AND THE VIRGIN ISLANDS IN ORDER TO AVOID THE DELAYS IN MAKING FUNDS AVAILABLE TO THOSE JURISDICTIONS AS OCCURS UNDER THE CURRENT LEGISLATIVE AUTHORITY.

- o A $700 MILLION APPROPRIATION LEVEL FOR THE HEAD START PROGRAM. THIS IMPORTANT PROGRAM IS NOW OPERATING UNDER THE CONTINUING RESOLUTION AT A LEVEL OF $625 MILLION. THE $75 MILLION FUNDING INCREASE WE ARE PROPOSING, INCLUDING A $55 MILLION SUPPLEMENTAL REQUEST, WILL PROVIDE HEAD START SERVICES TO 414,000 CHILDREN. 90 PERCENT OF THE CHILDREN IN THE PROGRAM ARE FROM FAMILIES WHO ARE POOR AND AT LEAST 10 PERCENT OF THE CHILDREN SERVED ARE HANDICAPPED.

- o $141 MILLION IS PROPOSED FOR THE CHILD WELFARE SERVICES PROGRAM. $85 MILLION OF THIS AMOUNT IS DEPENDENT ON THE ENACTMENT OF NEW LEGISLATION TO STRENGTHEN THE STATES' FOSTER CARE AND ADOPTION PROGRAMS. AS THE STATES IMPROVE THEIR FOSTER CARE AND ADOPTION SYSTEMS, THEY WILL ULTIMATELY BE ELIGIBLE TO RECEIVE FUNDING UP TO THE FULL $266 MILLION AUTHORIZATION LEVEL FOR THE CHILD WELFARE PROGRAM.

- o $559 MILLION FOR PROGRAMS AUTHORIZED UNDER THE OLDER AMERICANS ACT. THE $50 MILLION INCREASE OVER THE CURRENT LEVEL INITIATES NEW LEGISLATIVE AUTHORITIES RECENTLY ENACTED BY THE CONGRESS, INCLUDING:

  -- $23 MILLION FOR THE SEPARATE NEW NUTRITION PROGRAM PROVIDING HOME DELIVERED MEALS. IN TOTAL, THE 1980

NUTRITION PROGRAMS WILL MAKE $278 MILLION AVAILABLE TO THE STATES, UP $28 MILLION OVER THE FUNDS NOW AVAILABLE. IN ADDITION, OVER $50 MILLION IN FOOD COMMODITIES WILL BE MADE AVAILABLE UNDER THE AUSPICES OF THE DEPARTMENT OF AGRICULTURE.

-- $15 MILLION TO ESTABLISH PROJECTS IN 10 STATES TO EXPERIMENT WITH ALTERNATIVES TO LONG-TERM CARE FOR THE ELDERLY AND DISABLED. THESE RESOURCES WILL BE PLANNED IN CONJUNCTION WITH A LIKE AMOUNT OF MONEY BEING REQUESTED IN THE HEALTH CARE FINANCING BUDGET FOR LONG TERM CARE DEMONSTRATIONS. IN ADDITION, A NEW $10 MILLION PROGRAM FOR INDEPENDENT LIVING SERVICES, AUTHORIZED IN THE REHABILITATION SERVICES AMENDMENTS, IS ALSO PLANNED IN THE 1980 BUDGET.

o $817 MILLION FOR REHABILITATION STATE GRANTS IN 1979 AND 1980. THIS LEVEL FULLY FUNDS THE BASIC AUTHORIZATION AMOUNT IN THE 1978 AMENDMENTS AND IS $57 MILLION HIGHER THAN THE CURRENT CONTINUING RESOLUTION. WE ARE NOT PROPOSING TO FUND THE NEW PROVISION WHICH INDEXES THE AUTHORIZATION BASED ON THE RATE OF INFLATION. WE DO NOT BELIEVE THIS IS APPROPRIATE IN SERVICE RELATED PROGRAMS. LEGISLATION IS BEING PROPOSED WITH THE 1980 BUDGET TO REMOVE THIS PROVISION FROM THE 1978 AMENDMENTS.

SOCIAL SECURITY ADMINISTRATION

THE PROPOSED FISCAL YEAR 1980 BUDGET AUTHORITY FOR SOCIAL SECURITY PROGRAMS IS $130.2 BILLION, $16.3 BILLION GREATER THAN OUR CURRENT ESTIMATE FOR 1979. THE PRINCIPAL FACTOR IN THIS INCREASE

IS HIGHER INCOME TO THE SOCIAL SECURITY TRUST FUNDS CAUSED BY THE GROWTH IN THE COVERED POPULATION, RISING INCOMES, AND SCHEDULED INCREASES IN THE SOCIAL SECURITY TAX RATE AND THE WAGE BASE SUBJECT TO TAXATION.

TOTAL OUTLAYS FOR SOCIAL SECURITY PROGRAMS ARE ESTIMATED AT $129.5 BILLION IN 1980, $13.7 BILLION HIGHER THAN FISCAL YEAR 1979. THE INCREASE IN OUTLAYS IS PRIMARILY THE RESULT OF AUTOMATIC BENEFIT INCREASES TRIGGERED BY INFLATION. $10 BILLION OF THE TOTAL INCREASE IS FOR THIS PURPOSE.

ALTHOUGH MOST OF THE SOCIAL SECURITY BUDGET INVOLVES SPENDING FROM TRUST FUNDS WHICH DO NOT FALL UNDER THE JURISDICTION OF THE APPROPRIATIONS COMMITTEE, I WOULD LIKE TO BRIEFLY SUMMARIZE THE KEY ELEMENTS OF OUR 1980 PROPOSALS IN MY DISCUSSION OF THE SSA BUDGET.

THE HEW BUDGET FOR THE SOCIAL SECURITY PROGRAMS PROPOSES TO DISCIPLINE THE GROWTH OF ENTITLEMENTS BY:

-- REFORMING THE DISABILITY INSURANCE PROGRAM;

-- ELIMINATING MARGINAL OLD-AGE AND SURVIVORS INSURANCE BENEFITS AND SUBSTITUTING NEEDS-TESTED BENEFITS TO PROTECT THE POOR;

-- STREAMLINING AFDC ELIGIBILITY AND BENEFIT COMPUTATION RULES TO MAKE THE PROGRAM MORE RESPONSIVE TO GENUINE NEED AND LESS PRONE TO ERROR.

Disability Reform

The Disability Insurance program has been one of the fastest growing programs in HEW. The size of the caseload has nearly doubled since 1970. Our proposed reform seeks to strengthen the basic protection offered by this program by removing incentives to misuse it and strengthening incentives to return to the work force.

We are proposing to reduce benefits which, in our judgment, are inappropriately high.

-- Total benefits received by the disabled worker's family would be limited to 80 percent of predisability earnings, which approximates the disposable income which had been available to the beneficiary before becoming disabled.

-- The "drop-out" years provision in the budget computation will be made proportional to length of time in the labor force, to reduce inequities between younger and older workers.

We propose to strengthen work incentives by removing obstacles that deter people from returning to the work force.

Old-Age and Survivors Benefits

We are submitting legislation which will eliminate a number of marginal and duplicative Social Security benefits, while at the same time substituting needs-tested benefits for people most in need. We strongly believe that pruning some of the

INESSENTIAL WELFARE FEATURES OF SOCIAL SECURITY WILL STRENGTHEN THE BASIC INSURANCE PROTECTION OFFERED BY THE SYSTEM. REVISIONS SUCH AS THESE COULD LEAD TO A REDUCTION IN TAX RATES NOW SCHEDULED TO GO INTO EFFECT IN 1981 AND LATER YEARS. OUR MAJOR OASI PROPOSALS ARE:

-- GRADUAL ELIMINATION OF THE STUDENT BENEFIT AFTER AGE 18. THIS BENEFIT WAS ENACTED WELL BEFORE THE FULL RANGE OF FEDERAL STUDENT ASSISTANCE PROGRAMS HAD BEEN PUT INTO PLACE.

-- ELIMINATION OF THE $255 LUMP SUM DEATH BENEFIT IN OASI. IN OUR VIEW THIS BENEFIT HAS LONG BEEN OBSOLETE. IT IS ALSO A VERY SUBSTANTIAL ADMINISTRATIVE BURDEN, TAKING 1,000 STAFF YEARS OF EFFORT.

-- TERMINATION OF THE MINIMUM BENEFIT FOR NEW RECIPIENTS. PEOPLE WHO ARE IN GENUINE NEED WOULD RECEIVE HIGHER SSI BENEFITS TO OFFSET THE LOSS OF INCOME FROM THE MINIMUM BENEFIT IN OASI.

-- ELIMINATION OF THE PARENT'S BENEFIT WHEN THE YOUNGEST CHILD REACHES AGE 16. THIS PROPOSAL WOULD NOT AFFECT THE BENEFIT EARNED BY THE CHILD, WHICH WOULD CONTINUE UNTIL AGE 18.

THE NET REDUCTION IN OUTLAYS FROM THESE PROPOSALS AFFECTING THE OASI PROGRAM IS ESTIMATED AT $511 MILLION IN 1980 AND $3 BILLION BY 1984.

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Aid to Families with Dependent Children

Although the appropriation request for the AFDC program increases by $400 million in FY 1980 due to increases in benefit levels, the projected caseload is nearly level at 10.5 million recipients. There are many reasons for this phenomenon, but two of the most significant are the expansion of the Child Support Enforcement program and increased attention at both the Federal and State levels to reducing ineligibility and payment errors.

The Child Support program not only helps current AFDC recipients leave the rolls by collecting support owed by absent parents, but the availability of services to non-AFDC famiLes also prevents families from becoming dependent on welfare. I have set a goal of $1 billion in child support collections for AFDC families in 1980.

I have also set goals for reducing the incidence of fraud, abuse, and waste in HEW programs and a key element in that effort is lowering the error rates in AFDC and SSI. To help bring these rates down we are expanding our technical assistance to States -- particularly the large States with the highest error rates; creating a Management Institute to identify problems and foster inter-state solutions; and, designing and testing a national recipient register to help States check on multiple receipt of benefits and to verify income which recipients receive from Federal sources. In addition, HEW and OMB are co-chairing a task force to simplify the currently complex welfare eligibility process which contributes to high error rates, high overhead costs, and poor service to the public.

We are also proposing a number of legislative changes which will make AFDC more effective and easier

TO ADMINISTER, WHILE AT THE SAME TIME REDUCING COSTS FOR STATE AND LOCAL GOVERNMENTS AS WELL AS THE FEDERAL BUDGET. THE PRINCIPAL PROPOSALS ARE:

-- SIMPLIFICATION AND STANDARDIZATION OF THE WORK EXPENSE DISREGARD. OUR RECOMMENDATION IS MODELED ON THE DISREGARD PROVISION INCLUDED IN THE 1977 AMENDMENTS TO THE FOOD STAMP PROGRAM.

-- INCLUSION OF STEP-PARENT INCOME IN THE CALCULATION OF AFDC ELIGIBILITY AND BENEFIT LEVELS. WE BELIEVE THAT A STEP-PARENT'S INCOME IS AN AVAILABLE FAMILY RESOURCE, A PORTION OF WHICH SHOULD GO TOWARD THE SUPPORT OF THE STEPCHILDREN.

-- MONTHLY RESTROSPECTIVE ACCOUNTING. NEW LEGISLATION WILL REQUIRE STATES TO GRADUALLY PHASE IN MONTHLY RETROSPECTIVE ACCOUNTING FOR DETERMINING AFDC BENEFITS BY 1982 TO SIMPLIFY THE COMPUTATION OF BENEFITS AND IMPROVE THE ACCURACY OF BENEFIT DETERMINATIONS.

-- CHILD SUPPORT ENFORCEMENT. WE ARE PROPOSING A NUMBER OF REVISIONS TO THE CHILD SUPPORT ENFORCEMENT PROGRAM TO INCREASE CHILD SUPPORT PAYMENTS FROM ABSENT PARENTS.

THE BUDGET IMPACT OF THE LEGISLATIVE PROPOSALS AFFECTING AFDC IS A SAVINGS OF $212 MILLION IN 1980 GROWING TO AT LEAST $345 MILLION BY 1984.

REFUGEE ASSISTANCE

THE APPROPRIATION REQUEST PENDING BEFORE YOUR SUBCOMMITTEE PROVIDES FUNDS TO CONTINUE THE ONGOING CUBAN REFUGEE PROGRAM AND THE NEWLY ENACTED PROGRAM OF SUPPORT FOR SOVIET REFUGEES. NO FUNDS HAVE BEEN FORMALLY REQUESTED IN 1980 FOR SUPPORT OF INDOCHINA REFUGEE ACTIVITIES. LEGISLATION FOR THIS PROGRAM EXPIRES AT THE END OF THE CURRENT FISCAL YEAR AND NEW LEGISLATION IS CURRENTLY UNDER DEVELOPMENT.

THE BUDGET INCLUDES A $90 MILLION ESTIMATE FOR LATER TRANSMITTAL BASED UPON THE ASSUMPTION THAT 25,000 NEW INDOCHINESE REFUGEES WOULD BE ADMITTED DURING 1980. A REQUESTED $52 MILLION SUPPLEMENTAL IS ALSO PROPOSED TO MEET THE HIGHER COSTS OF LEGISLATION ENACTED FOR THE INDOCHINA PROGRAM FOR THIS YEAR AND TO SUPPORT A HIGHER LEVEL OF NEW REFUGEES THAN ORIGINALLY PROJECTED. HOWEVER, THE ESTIMATES OF THE NUMBERS OF NEW REFUGEES IS UNCERTAIN AND FUNDING LEVELS ARE TENTATIVE AT THIS TIME.

MR. CHAIRMAN, TO CONCLUDE, I WOULD LIKE TO RE-EMPHASIZE MY STRONG BELIEF THAT THIS BUDGET PRESENTS THE RIGHT BALANCE BETWEEN FISCAL RESTRAINT AND HEW PROGRAM PRIORITIES. WE CAN MAKE A SUBSTANTIAL CONTRIBUTION TOWARD THE PRESIDENT'S GOAL OF REDUCED INFLATION WHILE PRESERVING EFFECTIVE PROGRAMS AND LAUNCHING SOME SIGNIFICANT NEW INITIATIVES WHICH:

-- BUILD ON PAST PROGRAM SUCCESS
-- PROVIDE INCREASED ASSISTANCE FOR THE POOR AND UNDERSERVED
-- PROMISE SUBSTANTIAL FUTURE SAVINGS THROUGH PREVENTION AND INCREASED EFFICIENCY.

I BELIEVE THAT HEW CAN BE MANAGED MORE EFFECTIVELY TO REDUCE FRAUD, ABUSE, AND WASTE TO THE ABSOLUTE MINIMUM. OUR CURRENT AND FUTURE EFFORTS TO AVOID UNNECESSARY SPENDING ARE CRITICAL TO OUR OVERALL PROGRAM GOALS AND, TO A GREAT EXTENT, MAKE OUR NEW INITIATIVES POSSIBLE.

CHART PRESENTATION

Secretary CALIFANO. Mr. Chairman, if I may, I would like to submit my statement for the record in its entirety, and simply go through these charts. We have talked to your staff about proceeding that way, which I think will highlight most of the issues.

Chairman MAGNUSON. All right. It will be placed in the record in full.

Mr. Secretary, I think we will let you go ahead uninterrupted until the end, and the committee members can make such notes as they wish and then ask their questions. Or would you rather that we took portions of your statement—one at a time?

Secretary CALIFANO. Either way, Mr. Chairman.

Chairman MAGNUSON. All right, go ahead.

Secretary CALIFANO. Mr. Chairman, I want to start with a chart that you are the father of. It is a chart of the number of employees that HEW now funds, either in the Department or elsewhere. I think it is the last chart in the package before you. I thought we should start with it, particularly in view of the hue and cry of the States, of so many States, for balancing the budget.

Chairman MAGNUSON. Now, we have all of the Governors in Washington, D.C. today. They are around and they are all calling for some balancing of the budget. And I'm sure that they ought to be here to listen to this, instead of downtown passing resolutions, wanting State aid and balancing of the budget at the same time.

INCREASE IN STATE AND LOCAL GOVERNMENT EMPLOYEES

Secretary CALIFANO. Mr. Chairman, last year we reported that HEW funds about 1,146,000 employees. These are the equivalent of full person-years, people who are employed directly on the Federal payroll or indirectly, through HEW programs.

This year, Mr. Chairman, that total will reach roughly 1,187,000, employees. But over the 5-year period from 1974 to 1978, the employment of non-Federal employees funded by HEW has gone up 25 percent. Far and away the largest increase is in State and local government, which has increased from 558,516 in 1974 to 683,697 in 1978. That is the fastest-growing government in the world today, the U.S. State and local government. It is up by about 30 percent over that 5-year period.

Federal employment is up by only 13 percent over that 5-year period. And there is nothing in this country that has risen at a rate that low, including inflation, over that 5-year period. You will note that that period spans two administrations, Mr. Chairman. I would have to say that a large part of that is due to the care with which this subcommittee has reviewed the HEW budget and the attention which you have paid to direct Federal employment.

I wanted to start with this, because you were the one that first asked us to put this chart together, and it has become a very revealing picture of what is happening in this country today in the context of government.

Chairman MAGNUSON. From 1977 to 1978, you have only gone up in the Federal Government approximately, from 140,000 to 143,000.

Secretary CALIFANO. The State and local government is up from 658,000 to 683,000. I think if we were to talk about balancing budgets and an economy of that kind, and holding down employment, the place to begin is at the State and local government.

Senator EAGLETON. Before you remove that chart, I'm told—and I wonder if anybody in the room knows the accuracy of it—that total Federal employment—this is from last year's committee report: "It should be noted that during the past 10 years, the number of State and local government employees has increased 43 percent"—we're talking macro, the whole business—"while the number of Federal employees has increased by 1 percent."

And these figures are broken out, so if last year's committee report is accurate, and I have no reason to doubt it, in the totality of the Federal Government, in 10 years it has gone up 1 percent; the totality of employment at the State and local level in that same time period has gone up 43 percent.

Secretary CALIFANO. Mr. Chairman, I would note one thing in terms of these increases. A large number of the increases, in fact the overwhelming bulk of them, are in the Social Security Administration and reflect in another way the changing demography of this country and the graying of the Federal budget.

LIMITATION ON EMPLOYMENT

Chairman MAGNUSON. Let me ask one question: Is there a Federal regulation laid down on employment increases that when two people leave you only hire back one?

Secretary CALIFANO. We have had a freeze. We had a freeze, during which we had a regulation like that in effect. But the freeze has been lifted.

The thing that will dry up Federal employment between now and September 1979 is the Leach amendment which Congress passed last year in the Civil Service Reform Act. It requires that overall Federal employment by September 30, 1979, be down to what it was on September 30, 1977.

Chairman MAGNUSON. So instead of having this adapted to your own agency, there is a total matter over all Federal employment that takes effect?

Secretary CALIFANO. That is correct. Actually, due to the way that the Leach amendment level is allocated among the departments, in HEW we will be up 2,600 above our September 1979 limit. Again, this is largely because of the reality of the needs of our senior citizens and the social security program.

Senator SCHMITT. Mr. Secretary, do you have any estimate, or could you provide for the committee, an estimate of how much that increase in State and local government employment is a consequence of regulations of your Department?

Secretary CALIFANO. No, I can't give you an estimate on that.

Senator SCHMITT. Because that is a common complaint: They need people in order to administer the regulations that your Department hands down.

REDUCTIONS IN REGULATORY REQUIREMENTS

Secretary CALIFANO. It is a common complaint, but in many respects an unfair one. Most of this employment—and this is employment that we fund out of HEW; this is not total State and local employment—most of it is running grant programs, medicaid programs, things like that, and the tab that we pick up.

I would note—and we are going to release this in a more coherent way in a few weeks—since I have been Secretary, we have reduced the pages of regulations that HEW has issued, overall, by 11 percent. We have eliminated 11 percent of HEW's regulations. We are going to set that forth in more detail in a couple of weeks.

Senator SCHMITT. In the education area, administrator after administrator and teacher after teacher in New Mexico has commented to me that there is now a threshold that goes up every year, where it does not pay to go after a grant, just because of the cost of administering the grant. Now, at some point I think it would be useful if we had some indication on the employment side.

Chairman MAGNUSON. He will come to that, and we will go into a lot of detail there.

I would like the Secretary to proceed.

Secretary CALIFANO. I would note that the sharpest reduction in regulatory requirements has been the reduction we made in the education area. We have changed the reporting from annual to every 5 years, and we have sharply reduced the amount of information, and so there should be some relief there.

HEW SHARE OF FEDERAL BUDGET

Mr. Chairman, as you've noted—and this is the total HEW budget, including social security—the HEW budget is now 37.5 percent of the Federal budget in 1980. It was 36 percent of the Federal budget in 1979; it was 35 percent in 1975. It continues to rise as a proportion of the Federal budget.

Chairman MAGNUSON. You want to remember that in those charts you go back to 1965, and that social security was not included in those charts.

Secretary CALIFANO. These charts are corrected to include social security.

Chairman MAGNUSON. It was included in 1965?

Secretary CALIFANO. These charts include it.

Chairman MAGNUSON. It was not included way back in 1965, but it is now included. I understand the charts are corrected to include social security?

Secretary CALIFANO. That's correct, Mr. Chairman.

I would note that Defense is about 23 percent of the Federal budget in 1980. If you go back here when HEW was 20 percent of the Federal budget, Defense was about 43 percent. So there has been a dramatic change in the crossing of the lines.

Chairman MAGNUSON. Well, that is mainly because of social security being in the budget.

Secretary CALIFANO. No, Mr. Chairman, it is also because of the Great Society programs, which have had a phenomenal impact.

Chairman MAGNUSON. That was done because somebody was trying to prove that they were doing more for social needs than they were doing for defense.

Senator EAGLETON. Mr. Secretary, is the biggest single reason for the increase from the 20 percent in 1965 to the 37.5 percent the increase in social security benefits, plus medicare and medicaid?

Secretary CALIFANO. Yes, it is. I would say that, plus the education programs we are just coming to now, that are about $12 or $13 billion. But social security has risen, as the result of both the cost of living increases and the increase of the basic rate. One must remember——

Chairman MAGNUSON. Let me correct my statement that social security, plus medicaid and medicare, are responsible for the big amount.

Secretary CALIFANO. Yes, Mr. Chairman. But I think you also have to include education, which was down around $1 billion there and has increased to $12 or $13 billion.

ENTITLEMENT VERSUS DISCRETIONARY FUNDS

Senator SCHWEIKER. Do you have, Mr. Secretary, any breakdown of the entitlement aspect?

Secretary CALIFANO. We do.

Senator SCHWEIKER. I think that will clear up some of this.

Secretary CALIFANO. This, again, is the total HEW budget, designed to just give a quick picture of entitlement programs: Social security, AFDC, supplemental security income, medicare and medicaid, and a few others, black lung, over which we have little or no control; and the discretionary programs, which are $21.6 billion.

Put another way, 89-plus cents, almost 90 cents of every HEW dollar, go out under an entitlement program. We have some discretion in the appropriations process over 10 cents of every HEW dollar going out.

Senator SCHMITT. Would you explain why you have no control?

Secretary CALIFANO. Well, no control in the sense that the law has to be changed in order to change the amounts in this program.

Senator SCHMITT. But sometimes that has been misleading, I think, when you say "we have no control."

Secretary CALIFANO. That is why I changed the word to "entitlement" from "uncontrollable."

Senator SCHMITT. We do have control. It's just a question of are we going to exercise it.

FUNDING FOR PROPOSED LEGISLATION

Secretary CALIFANO. Mr. Chairman, this is the HEW budget by various components of the Department showing our requests, $60.8 billion, and what those requests would be if proposed legislation we're recommending is enacted, $61.3 billion.

As you can see, Mr. Chairman, we held departmental management level, knowing you wouldn't give us any more money for it even if we asked for it.

Chairman MAGNUSON. Well, here again, you say with proposed legislation. Those are items we're not going to consider until there is legislation. You know the rule on that.

Secretary CALIFANO. I realize that, Mr. Chairman. I just wanted to give you the full picture.

Chairman MAGNUSON. If the legislation passes the way you think it is going to be, that would be the picture.

Secretary CALIFANO. That is correct, Mr. Chairman.

Chairman MAGNUSON. How much is that?

Secretary CALIFANO. It is about $500 million.

Chairman MAGNUSON. OK.

PROPOSED SAVINGS

Secretary CALIFANO. Mr. Chairman, these are savings, again just to give the committee the overall picture; those requiring legislation first, and then those that we will achieve by administrative action.

The biggest single saving, hospital cost containment, is $1.7 billion in 1980. Other savings that would also require changes in the law would achieve a $2.8 billion reduction.

Chairman MAGNUSON. Now, wait a minute. The minus $2.8 billion is not in the budget, is it?

Secretary CALIFANO. It is not in your budget, no.

Chairman MAGNUSON. It is in your budget.

Secretary CALIFANO. It comes to a total of $3.3 billion.

Senator EAGLETON. So if we don't enact any of those changes, if we just reject them all, the budget is going to be up $3.3 billion?

Secretary CALIFANO. That's correct, Senator.

Mr. Chairman, these are savings we will achieve by administrative action. They are underway or will be shortly.

We intend to limit the way we reimburse malpractice insurance under medicare and medicaid. Currently we pay 40 percent of the malpractice insurance premiums in this country, although our clients receive only 12 percent of the malpractice claims. But we intend to narrow that percentage we pay to the proportion we receive.

We make some other changes in medicare and medicaid. The medicare quality control program largely involves the introduction of more sophisticated computer systems. We will make the goals we show here. My own judgment is that we will exceed them. For example, New York City, where we put computers in place to get accelerated billpaying, in the first few months we've saved $29 million, rejecting

duplicate bills that otherwise would have been paid and other bills. And in the first full year of operation, we expect it to reduce expenditures by $100 million in the medicaid program in New York City, kicking out the duplicate and other bills that have been paid in the past and that would have otherwise been paid.

There are other changes we will make in health care financing.

In the Social Security Administration, largely through tightening and controls in the SSI program, we have had some real success, we have reduced the error rate from 6.5 to 4.5 percent over the last couple of years.

We have not had similar success with the aid for dependent children program. The error rate is about the same as it was when I became Secretary. We are trying a new strategy, trying to identify error-prone situations in the major error States, and we hope to have reductions there.

In the student financial aid, reductions will be achieved by finally computerizing the BEOG's program so that we reject ineligible applicants and identify them early on, and by the collection of the student loans in the Government program and the campus-based program. All of these we will achieve administratively.

SAVINGS UNDER LETTER OF CREDIT OPERATIONS

Senator EAGLETON. What is "checks paid, letter of credit" under "new regulation"?

Secretary CALIFANO. Currently in the AFDC program, we pay the States cash and then they ultimately pay the bills. What we're going to do is begin to give the States letters of credit. What they do now is hold our cash as long as they can and earn interest on it. We will hold the cash and take the interest on it. In fact, we will save $400 million by doing that.

But there is a lot more to be saved; to do it, we will simply pay the checks off a letter of credit.

There is a similar savings realizable through requiring the States to pay their social security collections for their employees much sooner.

These are the major increases that we are asking, Mr. Chairman, in the budget. I will cover the increases for preventive health in a little more detail later. The child health assessment program requires new legislation, Mr. Chairman. It is a change in the medicaid law.

Other increases are for mental health—a good part of that will require new legislation—and alcoholism assistance reform.

Chairman MAGNUSON. Now wait a minute. On CHAP, for instance, that is not in this budget. That will require legislation?

Secretary CALIFANO. That's correct.

MENTAL HEALTH LEGISLATION

Chairman MAGNUSON. Now, what about mental health legislation?

Secretary CALIFANO. We will be coming up with new legislation to implement the report of the President's Commission on Mental Health.

Senator SCHWEIKER. Well, that is $90 million, Joe. I know you are offsetting—they have $90 million for the start of the new program, but they are offsetting it with $35 million in reductions. But all of that $90 million would take new legislation, and I think that is the point. We are going to be in a bind timewise, because unless we get the specifics through in time for this committee to act, why, we won't have something to look to the $90 million.

Secretary CALIFANO. We are going as fast as we can. We are due to get the mental health legislation up here early next month. But again, as you know, sitting on the authorizing committee as well as this committee, the time within which we can get it enacted is a problem, and I realize that. But the problem, as I understand it, arises due both to law and tradition.

Chairman MAGNUSON. What do you mean by title I concentration?

Secretary CALIFANO. Mr. Chairman, last year the Congress enacted a provision that added a provision to title I that says that in areas of high concentrations of poverty, rural areas where 20 percent or more of the children are title I eligible, or urban districts where 5,000 or more children are eligible, there would be additional funds available.

The $400 million increase fully funds that provision enacted by the Congress last year.

The $51 million increase for the Education for the Handicapped Act is authorized under existing legislation.

The desegregation assistance and bilingual education program increase is under existing legislation.

Under human development area, the $85 million increase for child welfare does require new legislation. The Head Start program does not and the aging programs do not.

Senator SCHWEIKER. I have a question on the education for student aid. Would you explain that?

Secretary CALIFANO. I have a whole chart there, Senator. Briefly, going to the health area, first, what has happened to the Federal health budget drives home a point you made, Mr. Chairman, about medicare and medicaid, because that is what most of the increase is.

The shaded area of this chart shows the Public Health Service budget in 1965. It was $1.6 billion, and there were $300 million going out to provide health care for some elderly. By 1980, in this budget, we see $44.5 billion for medicare and the Federal share of medicaid, and $7.7 billion for the Public Health Service.

INCREASE IN HEALTH CARE COSTS

A quick sense of the growth in health care costs, which I know you are familiar with, Senator Schweiker.

Mr. Chairman, you can see that the average health bill for each American in 10 years has gone from $334 to over $1,000; the average hospital bill per patient-day from $81 to $252.

In medicare, the number of persons enrolled has increased from 20 million 10 years ago to 27.5 million in 1980; and the benefit payments have increased from $7.6 billion to $31 billion in 1980. So the increase, of course, is in the phenomenal difference in the cost of those benefits during that 10-year period.

In medicaid, the people receiving assistance 10 years ago were 14.5 million; today the number is 23 million. And again, the Federal share, $2.6 billion 10 years ago and $11.6 billion today; again, the much larger proportional increase because of the increase in costs.

Chairman MAGNUSON. Now, don't forget, you still have a percentage trigger on health care as it pertains to the gross national product. It went up from 7.2 to 9.2 percent of the GNP, is that correct?

Secretary CALIFANO. Nine percent, basically.

Chairman MAGNUSON. That is up 2 percent compared to the gross national product.

Secretary CALIFANO. That is correct, Mr. Chairman.

The Public Health Service chart, just a quick breakout of our programs by the various agencies: the HSA, CDC, NIH, and the subtotal. Other than the Labor-HEW programs are not before this subcommittee. They include the Food and Drug Administration and the Indian Health Service.

PREVENTIVE HEALTH INITIATIVE

I mentioned the CHAP legislation, Mr. Chairman. There is a tremendous push in the President's budget for preventive health. Also, last year the Congress passed the adolescent health services legislation, teenage pregnancy legislation. We recommend full funding of that legislation, $60 million in fiscal 1980; and we would like $7 million in a supplemental in 1979 to start it up.

We would like to begin the demonstration grant program to improve maternal and child health, for $11.9 million.

The Congress enacted a new State formula grant program for prevention, to get the States more focused on prevention, and we ask for $18 million of the $20 million authorized in that legislation.

Fluoridation; we estimate we save $31 in medical bills for every dollar we invest.

And the control of hospital-based infections, which is becoming an increased problem in this country.

And we would like to do more significant research in the occupational health and safety area.

SMOKING AND HEALTH

Mr. Chairman, we would increase the research budget by about $5 million over 1980, the bulk of it in the Cancer and Heart and Lung Institutes, which represent the highest health tolls. We have $4 million in child health, much of it for behavioral research on preventing kids from starting to smoke; and then health education, which has a tremendous payoff in this area, we believe. And then we have money in CDC and the Office of the Assistant Secretary for Health.

Chairman MAGNUSON. What is that, O-A-S-H?

Secretary CALIFANO. That is the Assistant Secretary for Health and the funding for the basic health education program, Mr. Chairman. Every time the subject of the dangers of smoking is given wide publicity, the percentage of individuals who smoke goes down. And we are on a major effort now.

We will have new initiatives in alcoholism. They will not require legislation. They would be largely administrative actions. We are working on them, and we intend to announce them sometime in late April. We ask for $14 million for this program, directed largely at women and teenagers, where we have the sharpest increases, the same population that much of the tobacco program is directed at.

MENTAL HEALTH

New community mental health legislation, which Senator Schweiker mentioned. We will get this legislation to the Hill as rapidly as we can, including legislation to increase the maximum in medicare.

Chairman MAGNUSON. But there again, the budget provides $30 million in community mental health.

Secretary CALIFANO. That is the supplemental.

Chairman MAGNUSON. Then the $99 million, is that subject to legislation?

Secretary CALIFANO. Yes.

Chairman MAGNUSON. What is in the budget now?

Senator SCHWEIKER. Well, that is in the budget.

Secretary CALIFANO. That's right.

Senator SCHWEIKER. That was in the figure we saw.

Chairman MAGNUSON. The $99 million was put in the budget without authorization?

Secretary CALIFANO. These are increases, Mr. Chairman. What I'm saying is this $99 million assumes legislation enacting many of the recommendations.

Chairman MAGNUSON. Well, if there is legislation we will put it in.

HEALTH SYSTEMS REFORM

Secretary CALIFANO. In terms of health reform, we propose a large increase in HMO's, with a funding increase of $35 million in 1980, the largest increase in the history of the program. Senator Kennedy and Senator Schweiker have led some legislation in that area through the Senate. We think we can do a lot with it.

We will sharply increase the number of HMO projects. In the single past year we increased from 3 to 4 percent the number of people covered by HMO's over the year before. It is still a small proportion of the population, but we think that we can go even more rapidly.

Chairman MAGNUSON. You don't need any legislation for that?

Secretary CALIFANO. No, sir.

To strengthen medical resources in underserved areas, we would increase the National Health Service Corps funding. We would increase

by $30 million the community health center funding. No legislation needed here.

EXCESS HOSPITAL BEDS

We would like $30 million to test out ways of closing and converting excess hospital beds. We have 130,000 excess hospital beds in this country that we estimate cost the American people $4 billion in unnecessary dollars. We would like to start finding out how to close them—$28 million to increase training for family medicine.

Chairman MAGNUSON. You had better justify in some detail later on why it costs $30 million to close some hospitals.

Secretary CALIFANO. We will, Mr. Chairman. We can close a lot of them awfully fast if the Congress will give us the Hospital Cost Containment Act.

Chairman MAGNUSON. But you won't need the $30 million.

Secretary CALIFANO. We would still like the $30 million, Mr. Chairman, to see if there aren't ways we can encourage, for example, the transfer of those beds into long-term care beds.

This is the Health Care Financing Administration chart, basically covering medicaid, for this committee, where we are asking for $12 million. This $30 million is funding for PSRO's. This $7.9 billion represents payments that come into the health care trust fund.

We are asking for $35 million for research and demonstration projects. We say that among the various reasons why medicaid is rising as fast as it is rising is because we have not had enough of an opportunity to move with research and demonstration projects, and we need that money. Many of those projects lead to saving money.

Here is a potential for savings, Mr. Chairman, which might interest you. We do not ordinarily competitively bid our contracts for people who process medicare claims. We have effectively been prohibited by law from doing that, because the Congress said that the provider should pick that contract. We have used our demonstration authority in the last year to go with competitive bids.

We have done this in two places now. In western New York State, the cost today of processing a medicare claim is $3.08. Beginning in January of next year, we will process that claim under a competitive bid for $1.53. And the current processors submitted a bid 30 percent lower than we are now being charged.

In Illinois, by going out on competitive bids, we have reduced from about $2.80 to $2.07 the cost per claim beginning next year.

So we would like to get authority to go out on competitive bids, and have Congress remove the requirement that the hospitals pick the providers.

EDUCATION BUDGET

Now, a brief snapshot of the education budget. Elementary and secondary education; the student assistance programs, which I will go into in more detail. Higher education and these other programs, I will cover all of these in more detail, Mr. Chairman.

The big increases are in the new concentration provisions, which we felt was the most effective use of limited resources, concentrating on the poorest rural areas and the poorest urban areas.

Education for the handicapped is up modestly. It will keep us paying 12 percent of the additional cost of educating handicapped children.

Desegregation assistance is up $22 million, largely to give us the flexibility to move with magnet schools and other programs. We are convinced that, now that Congress has given us more flexibility, that we can use this money to ease the social strife on desegregation.

Bilingual education, up $15 million. Coupled with that, we are going to sharply focus that program on teaching children English as rapidly as possible.

Education quality and basic skills, up $9 million.

Senator CHILES. I've heard that for the last 3 years now.

BILINGUAL EDUCATION

Secretary CALIFANO. Not from me for 3 years. I think we are gradually getting on track in bilingual education, Senator. There has been tremendous confusion. The interest groups have been resisting the legislative purpose of the program.

They would like it to be a program to teach both languages. We intend to try to get that money focused on teaching English as fast as possible and, during the period when the child can't speak English, teaching the child both languages.

BASIC SKILLS MONEY

New legislation was enacted last year, Mr. Chairman, which we'd like to fund, both to provide some money so that States can have testing programs and remedial programs.

We would sharply reduce impact aid, as you can see, Mr. Chairman. We think in a tight and austere budget, this may be the year to cut a little of the fat from the impact aid program.

And we are holding the vocational education program level.

Mr. Chairman, Senator, this is the higher education program. Our intent is to fully fund the Middle Income Student Assistance Act. The differences in levels of numbers here between our staff and the Congressional Budget Office are functions of different assumptions, in part about the economic conditions and in part about the level of participation we will have in the program. If we are a little low, we will be back for the necessary funds. I don't think we are.

The basic grants program is up $156 million.

Chairman MAGNUSON. Now, we just passed a big bill last year. Are you asking for more legislation on this?

Secretary CALIFANO. No. This is all to fund last year's legislation.

Chairman MAGNUSON. I see. All right.

Secretary CALIFANO. It is up $156 million. It will fund the BEOG's grants at the full $18 million authorized by law. We think it will take care of everybody involved.

We would hold supplemental grants at $340 million. That is authorized to go to $370 million. It is the only piece of the middle-income student assistance program that we are not fully funding.

Chairman MAGNUSON. Where is your BEOG's, in your basic grants?

Secretary CALIFANO. Yes.

Chairman MAGNUSON. Shouldn't that be a minus rather than a plus?

Secretary CALIFANO. Yes, it should.

Chairman MAGNUSON. Last year, you were $500 million off. Are you on target now?

Secretary CALIFANO. I think we are closer, Mr. Chairman.

Chairman MAGNUSON. You were $500 million off last year.

Secretary CALIFANO. We were $500 million off in terms of an overestimate.

Chairman MAGNUSON. Yes.

ADMINISTRATIVE REFORMS FOR BEOG's

Secretary CALIFANO. I have to explain something, Mr. Chairman, that is happening in the BEOG's program. No applications were ever checked in the BEOG's program.

We have now put in a computer system to make a gross check, and we rejected hundreds of thousands of applications last year that had come in from students. The computer will reject applications for small reasons as well as larger reasons. We have given most students until March of this year, if their application has been rejected, to get reconsidered. A very small proportion of students have come in.

It is our judgment that there was probably a significant amount of leakage in that program, with thousands of students receiving funds to which they were not entitled and for which they were not eligible. We believe that we will pick most of that up this year. It won't all happen in a year. These estimates may bounce around for 2 or 3 years as you get a program like that in place.

Chairman MAGNUSON. Well, the basic thrust of the BEOG's law changes the law to take in more students and make eligibility better for the so-called middle-income class people.

Secretary CALIFANO. Yes, Mr. Chairman, it does.

There are two reasons why this number is lower: We think there will be less participation because there are smaller numbers actually eligible than we had thought before; and two is, we have a substantial carryover into 1980.

Senator SCHWEIKER. How much is that?

Secretary CALIFANO. It is about $700 million, a substantial carryover.

Incidentally, one of the disagreements we had with the Congressional Budget Office in estimating is in the participation rate of students. Actually, students are participating in 1978 and 1979, at a lower rate than we had estimated. They are down around 66 percent.

We have increased the work study program.

The direct loan program is down.

Senator SCHWEIKER. Why are you cutting that?

Secretary CALIFANO. That is the NDSL program, the campus-based program, in which this amount basically represents a capital contribution. We believe through enhanced collection methods we will be able to reduce the necessary amount of capital that has to go into the program. We don't think it will affect the number of eligible students.

I should say, Senator, in candor, that we are not doing as well with the campus-based collections as we are doing with the Government-based collection. But I think we have made some changes that will do better there.

GUARANTEED STUDENT LOAN PROGRAM

Funding for the guaranteed student loan programs, as you can see, is down as well. There we are having great success. We have cut down the backlog, which peaked at about 400,000 and is down to about 340,000. In the first 4 months of this year, we have collected over $10 million, as compared with $15 million from all of last year.

Senator SCHWEIKER. What about your default rate compared to last year?

Secretary CALIFANO. The default rate on the guaranteed student loans under the Government loan program is down from 13.7 percent in fiscal 1977 to 10.5 percent in fiscal 1978.

Senator SCHWEIKER. Do you have an idea where you're going to get that?

Secretary CALIFANO. Yes, we want to get it way under 10 percent.

Senator SCHWEIKER. Do you think you will?

Secretary CALIFANO. Yes, we will, in this program.

Now, the default rate in the campus-based program has not gone down. The loans in the campus-based program in default are going up. They are up to 700,000 loans from about 600,000.

I called in all of the associations. I have written to all the college presidents and said we're going to start disqualifying colleges and universities that don't drive their default rates down.

Senator EAGLETON. Now, that's what program?

Secretary CALIFANO. This is the Government loan program.

Senator SCHWEIKER. 10.5 percent you're saying now?

Secretary CALIFANO. Yes. We believe the current rate is about 9.8 percent. That is the first quarter of fiscal 1979. We think we can hold that. By fiscal 1980 we would like to get it down under 9 percent.

These estimates are based on a 9-percent default rate. We think we can get it under 9 percent.

Senator EAGLETON. I'm just curious. What are you doing, apparently rather well, to bring down the 13 percent to 10, and you hope to get it down to 9, but that the campuses are apparently doing so poorly?

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Secretary CALIFANO. We are collecting the loans. They are not trying. They can collect the loans themselves, but they have never tried to do it before because it is basically Federal money. It is not their money. I remind them that it is indeed not their money, but that they have an obligation to us to make collections.

Second, they can turn those loans over to us, in which case they lose 10 percent of the recovery out of their capital bank, which we get for collecting them. They haven't done this. I think now they will be starting to do it in a much more significant way, and I think we will be much better at collecting those loans. They are just not geared to do that.

I also think, as we start to invoke the power that Congress gave us to disqualify institutions from receiving those loans with high default rates, that they will start collecting, too. And we know they can do it, because the default rates vary in universities from under 10 percent to over 90 percent.

Senator EAGLETON. In some universities it is over 90 percent?

Secretary CALIFANO. Yes.

I think I have covered most of that.

BASIC GRANTS

Chairman MAGNUSON. Now wait a minute. You still anticipate in this budget that we have in front of us, without new legislation, that we will fund the BEOG's at $1,800 maximum?

Secretary CALIFANO. That's true, Mr. Chairman.

Chairman MAGNUSON. And which will average out to $940, which is up $50 over 1979. Now, would you put in the record somewhere what is the maximum received, so we can have that?

Secretary CALIFANO. Yes, we can do that.

[The information follows:]

The maximum basic grant award in fiscal year 1980 is $1,800. The largest grants—between $1,600 and $1,800—will be awarded to almost 310,000 students as follows:

Income category	*Number of awards*	*Percent*
Up to $5,900	119,718	39
$5,901–$11,100	141,006	46
Above $11,100	48,213	15
Total	308,937	100

Chairman MAGNUSON. And then, you still don't need any new funds for BEOGs?

Secretary CALIFANO. No, we don't, Mr. Chairman, if our estimates are right. And I think they are going to prove to be right.

Chairman MAGNUSON. Despite the fact that we suggested that BEOGs move up into the middle class?

Secretary CALIFANO. Yes, up to $25,000.

Chairman MAGNUSON. But the reason you say you won't need any extra money for BEOGs is that those who are receiving it are ineligible, and that therefore you are cutting out a lot of ineligibles in one

category, and you are able to move it up into the eligibles for the other categories?

Secretary CALIFANO. Yes. Also, Mr. Chairman, we're going to have a carryover of $700 million, approximately.

Chairman MAGNUSON. Well, we may take care of that for you.

Senator SCHWEIKER. Mr. Secretary, what was the key as to what the computer screened out in terms of the ineligible students?

Secretary CALIFANO. Everything from their income. In many cases, they just never filled out the income block. They never gave any indication of family income. You have to remember, the BEOGs applications were, by and large, not checked. They were just taken at face value. We are looking at a whole host of ways of doing this, and one simple way might be to just peel the income off the tax return.

I don't know if you have ever seen a BEOGs application form, but I hope you never do. It is terribly complicated. It has about 20 pages of explanation of how to fill it out, about an 8-page form. And we're trying to reduce the length of the form and the length of the instructions. We would like to get down to one form for all of these student programs.

Chairman MAGNUSON. Is it true that the highest percentage of loan defaults occur in proprietary or so-called trade schools rather than universities?

Secretary CALIFANO. I would say that the problems related to fraud—fraud by the institution or fraud by the student—seem to come from the proprietary institutions. But there are universities with 90-percent default rates.

Chairman MAGNUSON. Are they big universities or small?

Secretary CALIFANO. They are all kinds. I don't want to lay out the list of universities. All kinds of universities are at different levels of defaults. So it is not State schools or private schools or big schools. It is not a function of the kind of university. It is a function of the way the university is administering that program, as best we can tell.

Senator EAGLETON. Could you supply for the record later on those universities or academic institutions that have default rates in excess of some percentage?

Secretary CALIFANO. We are providing the university associations with lists of the universities and their default rates, and we can provide them to the staff.

[The information follows:]

The list of universities and their default rates under the direct loan program will be supplied to the committee staff.

Senator EAGLETON. What is going to be the regulation to punish? What is going to be the optimum level? Are you going to permit a 50-percent default rate? 40? 60? What?

REDUCING DEFAULT RATES

Secretary CALIFANO. What we're setting up is a system by which you reduce your default rate so as not to penalize the institutions—some of

the institutions with high default rates are very poor, or they are institutions with very poor clientele, both—most of their students are on welfare.

What we would like to do is have a system by which you have to get down, you have to reduce your default rate. Ultimately, we want to get them down to 10 percent or less.

I don't know if I'm being clear, Senator. An 80-percent default rate can't get to 10 percent in 1 year.

Senator EAGLETON. I realize that. But I think 90 percent or 80 percent is intolerable and we have to bring it down by graduated hunks.

SOCIAL SECURITY PROGRAMS

Secretary CALIFANO. These are the social security programs that are in this budget, Mr. Chairman: the aid for dependent children program; the SSI program; the refugee assistance program.

The administration is preparing new refugee legislation. It is still working its way through. There will probably be supplemental requests if that legislation is enacted.

This is black lung disease payments into the social security trust funds, and the salaries and expenses for SSA.

In the human development services areas, the big change in title XX funding is in 1979; the $200 million of that $2.9 billion was allocated to day care. In 1980, there is no allocation for day care. We leave it to the States to decide how they want to spend it.

An increase in child welfare services. You'll notice that that does require legislation.

Here, the Head Start program, a modest $20 million increase.

The aging program is a modest increase.

Rehabilitation programs have a modest increase.

That's it, Mr. Chairman.

Chairman MAGNUSON. Well, this is a good place for us to recess for 15 minutes. We have a vote upstairs.

[A brief recess was taken.]

PUBLIC HEALTH SERVICE HOSPITALS

Chairman MAGNUSON. I was going to ask you, Mr. Secretary, for some details regarding the Public Health Service hospitals. But as long as you are going to look at particularly the Seattle one tomorrow night, I will let these questions go until you can take a look at it. I think the efficiency and its work will speak for itself.

But there is a mandatory pay raise for, I think, for the Public Health Service hospital systems that will run around $12 million, and there is no request in your supplemental budget for that amount. We will have to take a look at it, because patient services and personnel, should they be allowed to operate at levels mandated by law, are above your own budget request.

I hope they won't have to eat up the so-called $12 million increase. We should keep a steady level of funding, in my opinion.

You are going to take a look at it anyway, will you not?

Secretary CALIFANO. I will, Mr. Chairman.

Chairman MAGNUSON. Now, you are proposing some pretty drastic increases for urban health programs. An example is $30 million more for community mental health centers. And in doing that, I understand the motives behind that. But you shouldn't cut back the Public Health Service hospitals, because they are, in effect, community health centers.

But anyway, you will take a look at it and take a look at the rest of them. You will find that there is some understaffing and some of the patient care is being cut back.

TITLE IX

Now, do you want to go into title IX?

Secretary CALIFANO. Title IX, Mr. Chairman? Yes.

Chairman MAGNUSON. I have been talking with some universities in the past month, and they raise the question of title IX regulations, the inclusion or the exclusion of football, basketball, and other revenue-producing sports from the title IX regulations.

One president of a university told me only today that it was his understanding that what HEW was about to adopt would cost that university about $200,000 to comply. He had no idea how the school could come up with that amount.

I think what they would like to know is where you stand in this controversy, and when will these regulations be issued, so they know where they are. They all want to exclude at least football. They can't see any reason why football should be included.

Secretary CALIFANO. Mr. Chairman, if they want to exclude football they will have to go to the Congress and get a law passed. We are operating under the statute passed by the Congress. President Ford wrote and submitted the title IX regulations to the Congress. The Congress had an opportunity to veto the regulations. They specifically include all revenue-producing sports. There were attempts on the floor to eliminate that, and these attempts were defeated.

It's clear the intent of Congress is to include revenue-producing sports. So I think if the argument is to exclude football, that should be addressed to the Congress and see whether the women's groups and the women athletes should make their case, and then the universities and the male athletes should make their case, and the Congress can decide whether to exclude football or not.

Our guidelines provide that special attention be paid to the unique status of particular sports in this respect: If equipment for the sport costs more, if the scope of the competition is different—national versus local—and any attendant cost on that, either in transportation or publicity or what have you. But we think that was adequate to take care of the problem in football.

We have received comments on the guidelines. We are now reviewing those comments, and we will issue the final guidelines within the next couple of months. We have done the best and fairest we could under these circumstances to comply with the law passed by the Congress, I think, on the whole, independent of any particular sport in the controversy at this time.

I think if athletics build character in men, if athletics teach leadership ability in men, teach the ability to learn how to win and how to lose and teamwork, there's no reason to think that that is only transmittable to men through athletic programs and it is not transmittable to women.

Chairman MAGNUSON. Well, I am not discussing the merits or demerits of the law. What I'm trying to get at is they seem to be a little bit up in the air as to what the final regulations are going to be. And once the regulations are published, why, of course, it would be up to Congress to make such changes as they want.

Secretary CALIFANO. Also, you should note, Mr. Chairman, that the universities by and large have asserted that there would be staggering costs for the handicapped regulations when Congress passed a law about discrimination against the handicapped, and those estimates have turned out to be grossly exaggerated.

There is tremendous compliance going on. The regulations in the handicapped area basically require that you make the programs accessible, not make structural changes.

Chairman MAGNUSON. Well, I'm sure they will be glad to hear that, because there was some confusion there.

Secretary CALIFANO. We recommended last year that $50 million be appropriated to help the universities adjust to the handicapped discrimination regulations, and this committee, among others, determined that there was not an adequate case made by us or the universities for that $50 million. And I would suggest, Mr. Chairman, that you look at this with the same care after the allegations by the universities on what the title IX compliance will cost them.

Senator EAGLETON. Mr. Chairman, I have a question both on title IX and the handicapped.

Chairman MAGNUSON. Go ahead.

Senator EAGLETON. Well, let me, if I may, do my title IX question. As the Secretary points out, of course, he's operating under the mandate of law. But there was a 1974 title IX amendment, the Javits amendment, that spoke in terms of: "Reasonable provisions, considering the nature of the particular sports."

EQUAL FUNDING FOR MALE AND FEMALE ATHLETES

Now, Mr. Secretary, let me ask you this: Does your policy interpretation require equal aggregate expenditures for members of each sex or for male and female teams?

Secretary CALIFANO. It requires, Senator, equal per capita expenditures for each sex, with the provision that the university make adjustment in how they determine what is a per capita expenditure, based—and this was designed to comply with that amendment you're talking about—based upon the nature of the particular sport. We specifically state in the guidelines that you can take into account the cost of equipment—football equipment, for example, is more expensive than equipment for a woman's soccer team—that you can take into account the scope of the competition—national competition versus local or State competition or regional competition.

So we have recognized that the expenses of a big football team are going to be higher. But in terms of the expenditure, we put it on a per capita basis and we put it on a per capita basis because if a football team has 11 members and a basketball team has 5, we don't want the same amount for the basketball team as the football team.

There has been a tremendous increase in the interest in sports among women, I think in large measure as a result of title IX, which has just been enacted by the Congress.

We do not believe the regulations we put out impose an undue burden on the universities. And not all of the major universities with big-time football, with big-money football, have complained about those regulations. Several of them have come in and told us they can comply and will be able to comply.

I think one of their greatest concerns seems to be that they want to be able to give more scholarships and larger scholarships to men than they give to women, and I don't think you can have a university in this country with a student body which is roughly equally divided between men and women that gives 100 scholarships to men and gives 5 scholarships to women. I don't think that's fair in the context of the law the Congress passed.

It is not an easy law to enforce, but when Congress passed it, President Ford then wrote very detailed regulations, which were subject to veto by the Congress. There were attempts in connection with those regulations, as in connection with the legislation, to exclude football or revenue-producing sports, which would include football and in some cases basketball and others. And the Congress had a major debate and rejected that proposal.

I think this question will ultimately be before the Congress again. We try to do the best we can. We will consider all the comments we have received, and wherever we think fairness or compliance with the law requires adjustments, we will make them in the guidelines we put out.

Senator EAGLETON. So the regulations will require an equal amount of money for athletic scholarships for men vis-a-vis women?

Secretary CALIFANO. On a per capita basis.

MEDICARE AND MEDICAID FRAUD AND ABUSE

Chairman MAGNUSON. Now, on the medicare and medicaid fraud and abuse, in October of 1977 we provided 90-percent Federal funding for States to set up their own fraud and abuse sections in the State medicaid agencies. How many units have been set up?

Secretary CALIFANO. Twenty-one fraud units have been certified by HEW, and we think 30 States will have units in place by 1980. Only three have served for more than 9 months. The States that have not moved with the units don't want them, basically. They make the argument that fraud is a relatively minor part of the problem. A few visible prosecutions and indictments of doctors or providers will have a tremendous deterrent effect; they don't need a unit to do that. What they're more interested in is units that would collect money that is mispaid through error, carelessness, or abuse, and that is where they want to put their resources.

And second, there is a lot of bureaucratic turf-fighting within the States. The unit might be in the Department of Human Resources or the Attorney General's office.

Chairman MAGNUSON. So you have no figure on whether they cost less than the amount they recover now?

Secretary CALIFANO. I would not look upon these units as being cost-effective in that sense. I'm not sure that that is the way we should judge them, Mr. Chairman. Money is going to be collected through the computer systems in most States, and not through these units.

RESCISSION OF CONSTRUCTION FUNDS

Chairman MAGNUSON. Now, we have a request for a rescission based upon the child health facility. The Congress provided $37 million for construction, and this has turned out to be quite a controversial issue. The President proposed that we rescind our funds for the construction of this project and apparently the White House feels, as you do, that the NIH intramural research program is strong enough, and in fact the universities should be doing any expanded programs in this area.

I understand some people would rather use that $37 million for research programs and not for construction.

Secretary CALIFANO. Mr. Chairman, I don't think that's the choice. We do not recommend rescission based on weighing that construction against research. We recommend rescission as a budgetary matter, and we recommend some other rescissions, too, which we would urge upon this committee.

The House Appropriations Subcommittee approved $61 million.

Chairman MAGNUSON. In other words, you don't want this as a tie-in?

Secretary CALIFANO. No, it is not related to that. It is purely a budgetary decision. It is just a budgetary decision.

The House did not grant our rescission request with respect to that building. It did in some other areas. And we would hope that this committee would perhaps grant all our rescission requests.

ADVISORY COUNCILS

Chairman MAGNUSON. All right, we will take a look at it.

Now, on the advisory councils, we have been getting a lot of complaints. There were 40 different advisory councils in HEW that were either not operating or appointments to them were late. Our information is that about 200 appointments have not been made.

The question is, what is holding all this up? Many of the health programs cannot pass on grants to schools and outside groups without the councils.

Secretary CALIFANO. Mr. Chairman, let me just put the question of HEW advisory committees in perspective. As of December of last year, there were 257 advisory committees in HEW, 3,381 members. Every year I have to fill 1,400 vacancies. I have to fill about 500 of these vacancies directly, and I have delegated the authority to fill about 900 to 1,000.

Most of the vacancies we're talking about are in the technical advisory committees advising the health area. For a couple of years, I have pressed very hard to increase the geographic distribution of those committees. It was as though we had an east coast and California, and nobody was capable of sitting on one of those committees that wasn't from one of those two places. I also want to increase the number of women and minorities in those committees. This has resulted in some delays in making those appointments, but there was terrible maldistribution in those committees.

I have now redelegated the appointing authority back to people below me.

Chairman MAGNUSON. Well, if you could speed it up the best way you can.

Secretary CALIFANO. Also, on a typical appointment, Mr. Chairman, we may have 6 to 10 candidates and anywhere from 10 to 30 congressional expressions of congressional interest in different candidates.

Chairman MAGNUSON. Well, you have to take them all into consideration.

Secretary CALIFANO. That's right. It takes time, Mr. Chairman.

IMPACT OF ETHICS LAW

Chairman MAGNUSON. Now, one matter which again probably relates back to Congress. There have been some serious questions raised about the possible impact of the new ethics law upon the agencies and departments, especially NIH. And I understand you have been taking a personal interest in this matter, and I wondered if you wanted to comment.

Secretary CALIFANO. Mr. Chairman, there is a part of that law that makes it a felony for someone to counsel, advise, consult, or assist in representing any other person concerning anything in the agency or the scope of his authority while he was in the Government, for 2 years after he gets out. We know that the nonprofit professionals and the other biomedical research people and the men and women who head the National Institutes of Health and the top education people, will, in the course of their career development, inevitably go back and run medical schools or go to research centers or go to universities or what have you. They will be involved in some of the issues they were involved with in their Government position.

And they have come to me in significant numbers and said that they will have to leave before the effective date of that law as it is now drafted.

Now, that provision was not in the legislation the President originally recommended, and I have urged that, to the extent something can be done by regulation, it be done. But to the extent the law needs to be changed, I urge that it either be changed or the effective date just be postponed until the Congress can consider it. I don't believe the Congress intended to do that to those people and to create the kind of a brain drain that I think it will create. I think at HEW we can lose as

many as 100 top-level people before July 1 in those areas because of their concern.

Chairman MAGNUSON. It works the same way the other way if you take a good man from a school. He has expertise in some phase of health, and say NIH wanted him for a year's work, he would be afraid to go to NIH because he could not go back to his teaching. It works both ways.

Secretary CALIFANO. There's no question that it is already having an impact.

Senator EAGLETON. When is the effective date, July 1?

Secretary CALIFANO. July 1, Senator.

Senator EAGLETON. Whose bill was that, Mr. Secretary?

Secretary CALIFANO. It was everybody's bill.

Senator EAGLETON. Well, who managed the bill? What committee did it come out of?

Secretary CALIFANO. I don't know whether it was Judiciary or Government Operations.

Senator EAGLETON. Well, has the appropriate committee—I'm on Governmental Affairs—has the appropriate committee been notified of this dilemma?

Secretary CALIFANO. I think the administration is now working on this. I think Senator Moynihan has spoken about it. Chairman Rodino on the House side has talked to me. I am sure you will hear from them, as I have.

CAPITATION

Chairman MAGNUSON. Now, on capitation, this budget expects medical schools to continue to provide medical education under the combined impact of the loss of capitation support while maintaining compliance with the wage and price guidelines.

Have you considered the combined impact of these?

Secretary CALIFANO. Mr. Chairman, we eliminated general capitation payments for medical schools, and we recommended a rescission last year. The House Appropriations Subcommittee last week adopted part of our rescission for last year.

At the same time, this year we had come up with an increase in the support for physicians in the primary care and family practice area, where we would like to see an increase of physicians. We recommend a budget increase of $38 million. We would urge the committee to do that. We think that by and large, we are headed for having too many doctors in the country; most importantly, too many specialists, when we need more general care, family practice types, and we need them better distributed. And we think our proposals will do that.

As far as NIH is concerned, we held the budget level. I realize that has an impact in terms of inflation on NIH. The adjustments we make in the individual institutes are designed to keep the same number of individuals and the individuals we need in research training. That is the purpose, so that we would keep the flow of manpower and womanpower in those programs.

We propose a $28 million increase.

STATE REAPPROPRIATION OF FEDERAL FUNDS

Chairman MAGNUSON. We will go into details on this later. At least 33 and perhaps as many as 44 States now require that Federal funds be first deposited in the State's general fund and then be reappropriated through the State's traditional appropriation processes by the State legislature, before they can get to the entitled recipients. In some cases, such funds have not gotten to the federally intended recipients.

Secretary CALIFANO. We are looking at that, Mr. Chairman. We have not found any serious instances yet. There are two things:

One: What the States do is get the Federal money and invest it. They earn interest on the Federal money while we await their appropriations process. We have not found delays in services even in those States that have laws like this.

I think the issue deserves inspection not only by us, but by the staff of this committee in some depth. I think the issue probably deserves a hearing of some kind.

Chairman MAGNUSON. There is a problem on SSI in the overpayments to medicaid. In many cases, SSI paid the full payment to people that were put in a nursing home where medicaid is already covering their board and room.

Has the administration taken steps to insure that timely information is obtained on admissions and discharge? Maybe somebody else can answer that.

Secretary CALIFANO. We can supply more detail for the record, Mr. Chairman.

[The information follows:]

SSI PAYMENTS TO MEDICAID

In a response concurring with a GAO audit regarding this issue, SSA in July 1977, established new procedures to have SSA district offices: (1) furnish copies of a special reporting form to all Medicaid facilities in their areas, and (2) work with those facilities to assure prompt reporting of SSI recipient admissions, discharges, etc. However, we do not believe that there is authority to mandate reporting by nursing homes themselves. The procedure HEW established requires States to fhave nursing homes participating in the Medicaid program report all SSI admissions to the single State Medicaid agency which in turn is required to report this information monthly to the SSA regional office.

Secretary CALIFANO. Let me just note, it goes to the problem, again, of having so many programs and the importance of getting all these programs cross-computerized, and that takes a long time.

BEOG's REGULATIONS

Chairman MAGNUSON. Now, you mentioned BEOG's regulations, and I believe you stated that you've got new regulations that will be cutting down on this?

Secretary CALIFANO. The application form?

Chairman MAGNUSON. Yes, the application form, and the extra paperwork.

Are these new regulations being implemented and requiring refunds?

Secretary CALIFANO. I will have to check that, Mr. Chairman.

Chairman MAGNUSON. Well, one school in my State says that they raised the tuition from $2,300 to $3,600, in order to comply with the regulations.

Secretary CALIFANO. I find that hard to believe. Mr. Chairman, if you could give us the name of the school, I will be happy to sit down and look at it.

MEALS ON WHEELS

Chairman MAGNUSON. Why did you cut back on the current level of $590,000 for Meals on Wheels?

Secretary CALIFANO. The legislation has a new provision that has funding for the Meals on Wheels served in the home. We are putting increased resources in Meals on Wheels.

Second, we're beginning to increase the cost-effectiveness of the dollars we're spending. I will give you one example. We have got a program in Philadelphia designed to get more meals per dollar through changing the contracting procedures. Instead of contracting with a sort of whole series of mom and pop operations for senior centers, we required the centers to go out with combined contracts to large providers of food, thereby reducing the cost per meal in Philadelphia by 21 cents per meal. Maybe we can do that in other places in this country. We don't have a wide enough area to know how successful we will be.

Again, there is a price for all of these efficiencies in terms of doing this. But I think that program can provide more meals for the same amount of dollars with better contracting procedures, particularly in large urban areas, with the larger contracts.

NIH FUNDING LEVEL

Chairman MAGNUSON. Now, we continually hear that funding for NIH is kind of on a roller coaster; it goes up and down. And it's hard for me to understand. When you look at the NIH budget, it got $2 billion 3 or 4 years ago, and you're only asking for $2.3 billion in 1980.

Can you explain if these people in fact have a legitimate claim to the fact that this is not stable funding at NIH?

Secretary CALIFANO. Mr. Chairman, I think that——

Chairman MAGNUSON. Now, I don't necessarily agree with this. But I hear it all the time from NIH people and people who look at NIH.

Secretary CALIFANO. Mr. Chairman, I think that NIH, by and large, is not on a roller coaster. It has been going up from year to year, as I indicated earlier. I put in motion an attempt to prepare a 5-year biomedical research plan that scientists from all over the country gave comments on about a year ago, and I hope within another 6 to 9 months we will be able to lay out such a plan.

One of the main purposes of doing that is to stabilize the NIH funding.

Chairman MAGNUSON. Now, I have several other questions for the record, and if we could have these and the transcript back within 7 to 10 days at the most, we would appreciate that, because we are trying to move along very fast, as you know, on the appropriation bills.

[The following questions were not asked at the hearing, but were submitted to the Department for response subsequent to the hearing:]

STUDENT SOCIAL SECURITY BENEFITS

Question: You have proposed cutbacks in Social Security benefits including elimination of payments to college students.

How many students would lose benefits under your plan?

What portion of this reduction will be made up by increased student assistance, according to your estimates?

Answer: Our estimates for potential offsets to phasing out the student benefits are incomplete due to a scarcity of data, particularly potential behavioral data. However, crude estimates of the possible increased costs under one education program, the Basic Education Opportunity Grant Program, follow:

1980	1981	1982	1983	1984*
	(Dollars in Millions)			
+15	+30	+43	+52	+52

Keep in mind that we did not propose the phase-out of the student benefit with the intention that a major portion of the loss would be mitigated by increased aid under other programs.

We believe the social security benefit is now superfluous to the other forms of post-secondary student aid funded by the Federal government through programs of the Office of Education (OE). In 1965 when the social security student benefit was enacted, total funding for OE's student aid programs was only $186 million. If this funding level had only kept pace with inflation, about $400 million would be available today. But, in fact, Federal aid to students through our educational assistance programs will amount to more than $6.5 billion in School year '79/'80. Since there was such a limited amount of Federal assistance available in 1965, there may have been a legitimate need for special help for the student whose parent was retired, disabled, or deceased. However, given the phenominal growth in the funding levels of the OE student aid programs since then, we believe this need is no longer there.

The cornerstone of the Federal government's student aid programs is the Basic Educational Opportunity Grant (BEOG) program. This is our principal student aid entitlement program under which a needy student can get a grant of up to $1,800 for school year '79/'80. Implicitly, the maximum $1,800 award level is more or less the amount we have set for ourselves as

*These estimates already take into account the expansion of the BEOG's program caused by the recently-enacted Middle Income Student Assistance Act.

the maximum degree to which the Federal government will assist a needy student to get a college education without any payback requirement. But what has happened in the development of our education policy over the years is that we have neglected to consider the very large amount of social security benefits, also Federal expenditures, as aid paid for or because the individual is engaging in post-secondary education. Consequently, there are numerous instances where Federal payments under these two programs alone amount to as much as $4,000 a year in student aid. As suggested by GAO, we believe this level of Federal participation in financing post-secondary education is much too large a commitment.

While the BEOG program, funded at $2.4 billion in school year '79/'80, is by itself no small program, other OE programs such as the Guaranteed Student Loan program (providing $2 billion in student loans in '79/'80), the National Direct Student Loan, College Work-Study, and Supplemental Opportunity Grants programs will all provide large infusions of student aid funds to supplement the BEOG support. We are not suggesting that these programs will provide a dollar for dollar substitute for the social security student benefit, but only that to the extent all other students have such Federal support available to them, so will the student who would now be without a social security benefit.

We estimate that about 360,000 undergraduate students will be affected by our proposal to phase out the social security benefit in the first year after enactment. Of that number 70 percent to 80 percent will be eligible to receive a BEOG award of some amount. The other 20 percent to 30 percent will be ineligible for BEOG's simply because they come from families with very sizable incomes and/or assets. For instance, a student coming from a family of four would be ineligible if the family's income in the preceding year were $25,000 or more. However, even these students would be eligible for a student loan.

Furthermore, the newly enacted Middle Income Student Assistance Act would provide us with even greater opportunity to help students affected by the social security phase-out. Of the 360,000 students affected by the social security phase-out in the first year, our conservative estimate shows 252,000 would be eligible for BEOG's. But had the Middle Income Student Assistance Act not been enacted, only 45 percent (or 161,000) of the students affected by the social security phase-out would have been eligible for a BEOG. As a result, any negative impact of the phase-out of student benefits under social security will be largely reduced.

PATIENT CARE POSITIONS

Question: The Public Health Service hospitals are terribly understaffed now. In fact, some patient care is even being cut back. Can you guarantee us that no more positions will be taken from the Public Health Service hospitals and patient care this year?

Answer: I can assure you that we shall continue to operate the Public Health Service hospitals in such a way that the quality of health care being provided to the American seamen and to other patients will not be compromised. In total, the Division of Hospitals and Clinics had an employment level of 5,566 on December 31, 1978, 25 positions below the 1978 budgeted position level and 50 positions above the level authorized for 1979. I have instructed the Public Health Service in their management of employment ceilings and hirings to give high priority to health care delivery activities.

NATIONAL HEALTH SERVICE CORPS

Question: Is the National Health Service Corps the only support option open to medical students?

Answer: The National Health Service Corps Scholarship program is not the only support option open to the medical students. For instance, the Department of Defense Scholarship Program; the Office of Education HEAL Program; the Health Professions Loan Repayment Program; and State and local scholarship loan programs are other options open to medical students.

Question: Is the Corps able to effectively use unlimited numbers of doctors?

Answer: The Corps has been growing very rapidly. However, I do think there are limits to the eventual size and number of assignments that can be made. In 1980 we are seeking an increase of 1,095 new assignees bringing total field strength to 2820. We are in the process of examining the total national need for health personnel in medically underserved areas. The National Health Service Corps will be the major source of assisting communities in meeting manpower needs. By maintaining the 1980 budget level for the National Health Service Scholarship, we can expect a Corps field strength of 5,884 available in 1988.

Question: Should the Corps be the only option for poor and middle class students who want to be physicians?

Answer: There are various sources of aid for students studying medicine. In addition to the National Health Service Corps Scholarship, there are loans especially for health professions students available through the Office of Education, as well as State supported scholarship and loan programs. These programs should give equitable consideration to applicants from poor and middle class backgrounds. Additionally, we feel that such persons may contribute substantially through their service in the National Health Service Corps program.

However, we also believe that service in the National Health Service Corps, other Federal, State and local programs or in private practices should be the option of the individual.

NEW POSITIONS FOR PUBLIC HEALTH SERVICE

Question: I believe Congress provided the Public Health Service with about an additional 200 positions in the fiscal 1979 Labor HEW Appropriations Bill. What has happened to those positions?

Answer: The fiscal 1979 Labor HEW Appropriations Act provided an additional 405 positions above the budget request for the Public Health Service. The position levels as specified in the Act have been allocated to the respective health agencies.

Question: Have they all been filled?

Answer: No, not all of these positions have been filled. There is always a gap between the authorized position levels and the actual on duty employment. It is not possible to keep all of the positions filled every day of the year.

Question: If some or all have not been filled, have you sent up a request for a rescission?

Answer: There is no need for a rescission request. According to the GAO advice to your Committee, the rescission and deferral provisions of the Budget Control and Impoundment Act apply only to budget authority and not positions.

MATERNAL AND CHILD HEALTH RESEARCH AND TRAINING

Question: Given the emphasis on preventive health in this budget, isn't there a certain inconsistency in the recommended decrease in research and training for the Maternal and Child Health program?

Answer: No, the funds are still being used for preventive purposes. Funding for the Maternal and Child Health research and training activities are being redirected to support an increase in preventive maternal and child health services. There will still be Maternal and Child Health research and training in the preventive health area, but at the level such that we would be funding only the most promising research and training programs.

NHSC AND GEOGRAPHIC MALDISTRIBUTION

Question: Only about 15 percent of all shortage areas are now being served by the National Health Service Corps, and although the Corps retention rate is rising, only a small percentage remain where they are assigned after fulfilling service payback obligations. Given these facts, what real impact will your budget request to increase the number of Corps professionals have on our geographic maldistribution problem?

Answer: By increasing the number of health professionals available for assignment and appropriately placing them in shortage areas, we are providing the residents of these areas access to health services. Without Corps intervention, these people would not be receiving services and the areas in which they reside would continue

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to be counted as health manpower shortage areas. Currently, the National Health Service Corps has 751 staffed sites in 525 shortage areas. This represents 30 percent of the designated shortage areas. The 1,725 National Health Service Corps assignees in 1979 have the capacity to provide services to 2.4 million persons; in 1980, the 2,820 National Health Service Corps assignees will have the capacity to serve 3.9 million persons. This represents a 63 percent increase in the persons who will receive services as a result of increasing the number of National Health Service Corps professionals.

In addition, the increased staffing of shortage areas provides increased numbers of health professionals practice experience in these areas and may help to eliminate the stereotyped images of shortage areas and to increase the probability of more individuals considering permanent health manpower shortage area practice. The definition of retention implies a continued effort to provide health services in health manpower shortage areas. Any National Health Service Corps health professional who extends beyond the initial tour -- 2 years -- will continue to provide services and be retained as an appropriate health resource for the area. An extension, even for a year, provides another year's commitment that may influence a professional's long range plans for an underserved area.

NURSE TRAINING

Question: The President vetoed the Nurses Training Act, and his 1980 budget contains no support for nurse education. On what data are you basing your assertions that we have enough nurses, especially in light of the extremely low unemployment rate of nurses and the constant high demand for nurses across the country?

Answer: Significant growth has taken place in the nursing supply over the last decade. We anticipate that growth will continue, although at a slower rate. In order to determine future requirements, there have been several studies conducted on the future supply and demand for nursing services. In addition to those conducted or supported by the Department, the Congressional Budget Office (CBO) has also studied the adequacy of projected supply. Each produced a number of different estimates dependent upon particular assumptions related to the utilization of nurses and for the delivery of health services. In general, assuming no dramatic change in the health care delivery system, the overall supply and demand is expected to be in fairly good balance.

Question: Given the different types of nurse professionals, how do you propose to address the disparities of shortage within the nursing profession?

Answer: The need to prepare nurses for primary care responsibilities will be addressed through support for nurse practitioner training programs. Disparities such as inequitable geographic distribution and under-representation of minorities in the profession will be addressed through special project grants, but more so through the increased establishment of community health centers and National Health Service Corp sites in medically underserved areas. Prior experience has shown that as these organized comprehensive care

settings develop, nurses are attracted to work in areas previously neglected.

Question: Health planning legislation increasingly expands the role of the nurse. Has the effect of the changing role on the supposed oversupply of nurses been considered?

Answer: Increased utilization of nurses and expansion of the role of the nurse were among the assumptions examined in the various modeling efforts. Besides the expansion of the role of the nurse and at what magnitude, to assure an adequate supply of nurses in the future also depends upon other variables such as the form that National Health Insurance will take and the level of health care expectations.

Question: What would your National Health Plan do to the demand for nurses at all levels of skill and training?

Answer: The overall demand for nurses would not be seriously affected. The need for nurses with specified types of skills could be addressed through use of targeted support -- special project grants and nurse practitioner training grants.

HEALTH MANPOWER RESCISSION

Question: You are proposing a $168 million rescission in 1979 for Health Manpower programs. Explain the reasoning behind this proposal, including the effects of such a sizable reduction.

Answer: With the growth in output of health professions schools in recent years, there are reliable indications that we may now be educating enough health personnel in the aggregate to meet currently foreseeable health care needs. In view of the impressive progress that has been made toward the goal of providing for an adequate supply of health professions personnel, the Federal Government does not need to continue emphasizing programs of basic assistance for health professions schools and students.

The Nation's major health manpower needs today are those of improving geographic distribution, increasing the proportion of health professions students entering primary care specialties, raising the productivity of professional personnel, and improving health career opportunities for the disadvantaged. The budget for 1980 carefully targets support of such programs as family medicine residency training, National Health Service Corps Scholarships for students who commit themselves to serve in shortage areas, primary care, development of sound health manpower data, and assistance to disadvantaged students.

Question: How can you be sure that this curtailment of Health Professions Training funds will not result in a shortage of health professionals at some time in the future?

Answer: We have made very detailed studies of potential future supply and requirements employing different methodologies and alternative assumptions about possible changes in the health care delivery system. Our best technical judgment is that health manpower supply and demand in most disciplines will be in approximate balance, assuming no significant reduction from current levels in educational capacity or student enrollments. We feel that the presently antici-

pated supply will be about equal to requirements in 1990, and that any shortage or surplus would be slight and have only minor effects.

CLOSURE AND CONVERSION

Question: How would the $30 million requested for closure and conversion of unnecessary hospital beds be distributed?

Answer: The purpose of this program is to assist in the voluntary retirement of excess hospital capacity by providing grants to mitigate associated financial barriers. Applications will be reviewed at the Federal level. Priorities in distributing the funds will favor those proposals that contribute most to the above purpose. Further, special attention will be given to proposals that support local planning goals or are submitted jointly with local planning agencies. Proposals affecting multiple institutions, either through existing or ad-hoc associations, will also receive priority consideration.

Because of the first-time nature of this program, and because of the importance to health cost containment of understanding the effects of reducing excess capacity, we would also propose to acquire information from approved projects in order to assess these effects and to determine whether, and what kind of future Federal programs in this area are required. Thus, we would reserve a major portion of the funds available for those projects that could conform to specific requirements of experimental design developed to measure the aggregate benefits of closure.

Question: Would the HSAs and other local health planning bodies have a role to play, as the Senate health planning bill envisions, or would HEW make all the decisions at the Federal level?

Answer: HSAs will be required to review and approve proposals from projects located in the HSA geographic area. Since these agencies have a responsibility to foster the reduction of excess health care capacity in their areas, we would also expect that proposals for grants will arise as a result of the HSAs performing their normal planning activities. Furthermore, special priority will be given to applications for closure and conversion grants forwarded and supported by HSAs or SHPDAs.

HOME HEALTH

Question: The virtual elimination of the recently inaugurated home health support program appears to be inconsistent with the Administration's initiatives. Please explain this reduction.

Answer: The Home Health Service program has completed its objective by demonstrating that small amounts of funding to dedicated local groups can be effective in the development of new and the expansion of existing home health agencies. In addition, the program since its inception in 1976 has demonstrated, based upon comparative costs of $26 per home health visit and $243 per day for inpatient hospital services, that home health services are cost effective. As a result of this accomplishment, we believe that State and local governments through the use of public funds and funds available from private sources such as charitable organizations and private foundations could finance Home Health Services to the population in need. Also, Medicaid reimburses for home health services, and in 1980 estimates that the Federal share will be $154 million.

GAO REPORT-SMOKING AND HEALTH

Question: You are requesting $45 million for an anti-smoking strategy of education and research. Yet, a recent GAO report criticizes your existing anti-smoking campaign as ill defined, fragmented and unfocused. In light of this report, what steps are you taking to ensure that any new funds appropriated for this purpose will be used in an effective way to meet defined goals?

Answer: The GAO report was entitled "Difficulties in Evaluating Public Affairs Government-wide and at the Department of Health, Education, and Welfare" and, as its title indicates, addresses the Department's public affairs activity in general. A response to the report is being prepared under the direction of the Assistant Secretary for Public Affairs. I will be pleased to forward a copy of the response to this committee.

Smoking and health is included in the report in response to two Congressional interests -- is HEW justified in undertaking research and education in this field, and if so, are these programs being managed effectively?

On the first point, the report found that the Department is indeed justified in pursuing its educational and research efforts. Legislative authority exists for this effort and the health and economic consequences of smoking require it. On the second point, however, the report criticized the Office on Smoking and Health for what it described as a lack of any clear definition of goals and because it believed there was at that time insufficient documentation to support budget estimates for public information.

GAO completed its audit in August 1978, three months after the Office on Smoking and Health became operational. In our opinion the criticisms of the Office at that time were unjustified, but in any case the question is now moot. The Office is now almost a year old, and it has an effective program in operation. The publication of the Surgeon General's Report last January, a monumental contribution to the public and scientific understanding of the smoking problem, is an example of its planning and management capabilities.

INTRAMURAL RESEARCH

Question: In your opinion, has the NIH, both physically and programmatically, grown about as much as it should grow in terms of intramural research?

Answer: I believe that the size of the manpower pool which is conducting research on the Bethesda campus is probably optimum. Major increases in the number of persons employed would yield diminishing returns. The quality of the research effort would, in my judgment, not necessarily be improved by expanding the program beyond its present level.

CETA - VOCATIONAL EDUCATION

Question: The Committee is constantly receiving complaints about the lack of cooperation between CETA prime sponsors and vocational education institutions. The CETA people blame the vocational education people who, in turn, blame the CETA people. Whatever the situation, it appears that there is little cooperation between CETA programs and vocational education programs. What are you doing to help provide closer cooperation and coordination between CETA and vocational education?

Answer: In the spring of 1978 Secretary Marshall and I signed a joint memorandum of understanding which outlined a series of national objectives for the coordination of education and work programs, and the establishment of an interagency coordinating panel to achieve these objectives. The objectives include the dissemination of information to school districts about their role under the Youth Employment and Demonstrations Project Act, the identification of new education and work model programs, the assurance of program quality, the assessment of alternative education approaches, the improvement of occupational and career information, and the promotion of work and education councils. Over the next year HEW and Labor plan to initiate a series of major national projects, including the funding of 20 joint school district-prime sponsor model projects, programs for special populations--the disadvantaged, handicapped, and limited English speaking, and improved coordination between already organized local community groups.

Question: Does HEW have a formal, established mechanism to work with the Department of Labor to insure that CETA and vocational education programs are better coordinated at the Federal, State and local levels?

Answer: An Interagency Coordinating Panel between HEW and DOL has been established to assure collaboration in program planning, policy development, program design and program implementation between vocational education and CETA programs at all levels. I sent a letter to Secretary Marshall on January 16, 1979, informing him that HEW has appointed six members as part of the Panel and requested that he transmit DOL's list of panel members to HEW. Upon receipt of DOL's list, a meeting of the joint membership can be held.

Question: Are you currently working with Labor to provide for efficient implementation and operation of the funding setaside for vocational education in the new CETA authorizing legislation?

Answer: The Office of Education staff, particularly the Bureau of Occupational and Adult Education (BOAE), have been working with DOL staff on clarification of the regulations in order to set a base for the efficient implementation of the funding setaside for vocational education in the CETA authorizing legislation. Moreover, a unit has been established in BOAE for coordinating with DOL as well as monitoring the vocational education setaside to ensure the proper use of these funds. Ten States will be reviewed each year for this purpose.

EFFECTIVENESS OF VOCATIONAL EDUCATION

Question: Last year you wrote the conferees on the fiscal 1979 Labor-HEW Bill. In your letter you said "vocational education is one of the Department's least effective programs..." What is the basis of this statement? What are you doing to eliminate what you consider to be the ineffectiveness of vocational education?

Answer: The point of my letter to the conferees was not to criticize vocational education programs. All of my comments were made in the context of the Administration objective to hold down Federal spending and to target Federal spending where Federal dollars are of more significance. I believe that the vocational education program is an important one that has made and continues to make significant contribution in training thousands upon thousands of Americans for productive careers of work. However, since States overmatch Federal spending so substantially, we believed that program needs would be met without increasing Federal funds.

Question: Why did it take over two years for the Department to name a Deputy Commissioner for Occupational and Adult education?

Answer: The Office of Education underwent an extensive recruitment process at the Federal, State and local levels in order to select the most qualified applicant for this position. Usually, the most qualified applicants for this type of employment are already employed in high level positions in State and local governments. The delay in filling the Deputy Commissioner position is unfortunate, but has been necessary in order to select the best possible person. After interviewing and negotiating with several applicants, we have chosen Daniel B. Dunham as the Deputy Commissioner for Occupational and Adult education, whom we believe is the most qualified person for this position.

GUARANTEED STUDENT LOAN PROGRAM

Question: We continue to see GAO Reports and newspaper articles referring to the fraud and abuse imbedded in the Guaranteed Student Loan Program. The last GAO Report pointed out that it's been ten years now that the Office of Education's accounting and computer systems have failed to provide accurate financial data on Student Loan Programs. Would you describe for us what steps you've taken to shore up that program and inject some credibility and accountability into it?

Answer: Several steps have been taken to improve both the financial accounting and the program operations of the Guaranteed Student Loan Program. Most of the problems pointed out in the GAO audits, relating to various financial aspects of the Student Loan Insurance Fund, are accurate. Several efforts made in the past to deal with these problems were unsuccessful. However, recently, the Office of Education's Bureau of Student Financial Assistance established a task force to look into accounting

system for the Guaranteed Student Loan Program. The group presented its recommendations earlier this year and we are now looking at these recommendations and studying how we can implement them and correct the accounting problems cited by GAO.

With regard to program operations, the Office of Education has been systematically addressing problems in the Guaranteed Student Loan Program's computer program support area. An operating system has been developed that supports one of the largest collection systems in the Nation. The Office of Education has sent out approximately one million letters to borrowers, established a billing system, installed an automated skip-tracing system, exchanged addresses with the IRS, and put accurate and timely information on our collectors' desks. This has led to a quadrupling of the GSL collection rate, to more than $30 million a year, and the placement of over 150,000 accounts into a repayment or closed status.

GUARANTEED STUDENT LOAN PROGRAM:
FEDERAL EMPLOYEES IN DEFAULT

Question: We understand that about 7,000 Federal employees have defaulted on their student loans. What action has been taken against these employees and how many are presently making payments on their loans?

Answer: The Office of Education's records indicate that 6,917 Federal employees have defaulted on their guaranteed student loans. We have also found that 317 of these employees work for HEW. The following table indicates the status of these employees as of March 1, 1979:

	Total Federal Employees	HEW Employees
Paid in full	598	26
In repayment	3,014	94
In litigation	120	48
Written off	321	12
Death, disability, and bankruptcy cases	136	23
Unresolved cases	832	--
No longer employed by Federal government	1,896	114
	6,917	317

STUDENT AID: OVERPRICING BY INSTITUTIONS

Question: What information does the Office of Education have on the extent to which schools may be overpricing their cost estimates so that students may qualify for more Federal assistance?

Answer: The Office of Education has no information of widespread abuse on the extent to which schools may be overpricing their cost estimates so that students may qualify for more Federal Assistance. The level of tuition and costs of education are institutional decisions. However, the Office of Education is concerned about the impact of the availability of financial assistance upon institutional tuition levels and costs. This concern will be addressed during the reauthorization process.

GUARANTEED STUDENT LOAN PROGRAM

COMPUTER CONTRACTS

Question: Since 1967, we have appropriated $50 million for computer support systems, yet we still don't have a complete listing of all outstanding Federally-insured loans. We noticed that this past summer the Office of Education solicited bids for yet another computer system. How many different computer contracts are currently being performed that deal with student loans?

Answer: The Office of Education currently has four computer contracts totaling $8.2 million. Descriptions of these contracts follows:

Contractor/purpose	Amount in millions
On-Line Systems, Inc. (OLS) Pittsburg, PA Handles billings for interest subsidies, defaults claims, collections, etc. Primary computer support contract.	$5.3
Systems Management Associates (SMA) Norfolk, VA Provides data entry services (keypunching) for all documents; edits and stores these documents.	1.5
Rehab, Inc. Arlington, VA Provides skip-tracing services to lenders to help locate student borrowers.	1.4
Psi-Tram Arlington, VA Writes computer programs that are used by on-line systems for its Guaranteed Student Loan billing activities.	--1/
	$8.2

1/ Contract is for $10,000.

STUDENT AID: MONITORING

Question: Does the Office of Education have access to SSA, Veterans Administration or Income Tax files on a routine basis for monitoring of Student Assistance programs?

Answer: The Office of Education does not have access to Social Security, Veterans Administration or income tax files on a routine basis for monitoring the student aid programs. However, some data from these sources are available for use in determining the appropriate award under the Basic Grants program.

In the Basic Grants program during the 1979-80 award year, the Office of Education is matching Social Security files against the Basic grant applications to insure accurate reporting by students of their Social Security benefits. The Office of Education is currently finalizing the process to duplicate this procedure with the Veterans Administration with regard to veterans benefits. Information from the Internal Revenue Service (IRS) is not part of the routine validation procedures. However, statistical matches of IRS data to Basic Grant applications are being made in order to ascertain the extent to which income information is accurately on the Basic Grants application.

DIRECT LOANS

Question: HEW published regulations in 1978 which set minimum standards of fiscal and administrative capability for participating institutions. I understand that these regulations also established a formula to reduce funds to institutions with high default rates. Did you follow through and reduce funds to some schools?

Answer: The Office of Education is currently in the process of determining Direct Loan funding levels for the 1979-80 award period. Some institutions will be receiving less Federal capital than they otherwise would be entitled to because their default rates are in excess of amounts set forth in the regulations.

Question: Your January 29 announcement said that you "intend to" take over the collection of older defaulted loans. My understanding is that you intended to take over these accounts when you acted last year. How will you take over these accounts this time?

Answer: The procedures that institutions must follow in assigning loans that are two years or more in default to the Office of Education have been greatly simplified. To encourage institutions to act promptly, loans assigned to the Office of Education during the next year will not be included in the calculation of an individual institution's default rate.

DIRECT LOANS

Question: I understand that many of the people who fail to repay their loans are people who are earning a gainful wage and are financially able to repay the loans. What does the Department know about the financial status of defaulters?

Answer: There is no established profile for borrowers who fail to repay loans in the Direct Loan program since the program is administered by over 3,000 institutions. New HEW initiatives to curb defaults stress the point that an institution's management of the Direct Loan program and its willingness to apply due diligence in the making and collection of the loans have a strong impact on the default rate of that institution.

Question: Is it true that the schools with the highest default rates are not colleges and universities, but rather are small trade schools? How much of the program do they represent?

Answer: The default rate for proprietary institutions is 33.10 percent. This rate is exceeded only by the 34.95 default rate for all public two-year community colleges. The national average default rate for all institutions is 17.37 percent.

Question: What is the effect of these defaults on the chances of other students to receive NDSL loans?

Answer: Every dollar that is not collected on defaulted loan is a dollar lost to present and future students in need of financial assistance.

Question: Can you guarantee us that your plans to reduce the national default rate will be operational by the 1980-81 school year, as you said in your January 29 statement, or do you think that the mere threat of cutting off funds will cause schools to pursue violators more vigorously?

Answer: The plans to reduce the national default rate as announced on January 29 are currently being implemented. In addition to the punitive action of terminating Federal capital contributions if the institutions do not improve their administration of the Direct Loan program, the Office of Education will provide technical assistance where needed and provide tools such as skip-tracing assistance through the Internal Pevenue Service. It is expected that institutions will respond to our efforts by more vigorously administering all facets of the program, including the making, servicing and collecting of the loans.

STUDENT AID: COST SAVINGS

Question: With respect to student financial aid programs, your estimates for reduced funding are to a degree based on your efforts to curb fraud and abuse. Would you please outline for the Committee these efforts, the cost of these activities, and the actual savings realized.

Answer: In an effort to curb fraud and abuse, the Office of Education implemented improved quality control procedures and improved their financial management procedures in the administration of student aid programs. It is expected that the following initiatives will produce savings of at least $405.3 million in FY 1979 and $394 million in FY 1980:

--Increased Recovery of Guaranteed Student Loans in Default: Since the reorganization of the Bureau of Student Financial Assistance, several steps have been taken to reduce the number of loan accounts in default under the Guaranteed Student Loan program. During fiscal years 1978 and 1979, the Department requested and the Congress approved the addition of over 1,000 staff for loan collections (under 5-year part-time term appointments). In addition, OE contracted with private agencies in two regions to carry out collections activities. As a result of these steps and the adoption of straightforward management practices, the number of defaults has already been significantly reduced -- from a March 1978 peak of 400,000 loans amounting to $430 million down to fewer than 350,000 loans totaling $407 million at the end of 1978. The Office of Education will continue to aggressively pursue this initiative.

--Validation and Editing of Basic Educational Opportunity Grant Applications: Savings of $300 million in FY 1979 and $200 million in FY 1980 are projected for the Basic Grants program. These savings will be accomplished through improved procedures for reviewing the information provided by students and parents applying for Basic Grants. An improved computer edit system has been implemented to test the completeness and consistency of financial information. If the data provided on an application fails the edit checks, the applicant is asked to provide additional or clarifying information. If, after edit procedures, the information provided on an application seems suspicious, the applicant will be asked to provide documentation to support the accuracy of information reported. This information must be submitted to and validated by institutional financial aid officers before a grant is awarded. As a result of these actions, it is expected that, in many instances, awards will be reduced due to the improved accuracy of information reported on the Basic Grant application form.

--Identification of Improperly Disbursed Funds: In FY 1979, the Office of Education plans to conduct comprehensive reviews of student financial assistance programs at approximately 600 institutions. These reviews cut across all aid programs -- both grants and loans -- and often result in the identification of improperly disbursed Federal funds. An average of $45,000 in misspent funds is identified per review. Once identified, terms are arranged for repayment of the funds to the Federal government.

--Increased Recovery of National Direct Student Loans in Default: The Secretary recently announced a series of steps designed to reduce defaults in the Direct Loan program. First, regulations will be developed for the 1980-81 academic year that will set performance standards for the reduction of default rates at individual institutions. The proposed regulations will provide that institutions which do not meet these standards will have their Federal funding reduced or terminated. Second, the Office of Education intends to take over the collection of loans which have been in default for more than two years. The same collection techniques that have been used successfully Guaranteed Student Loan program will be applied to these loans. By returning their older defaulted loans to the Department, institutions will be able to devote more resources to the collection of newer loans which they continue to hold. Finally, the Office of Education will expand technical assistance and training for institutions that need assistance in improving the management of their loan programs. The increased collections resulting from these administrative actions will reduce the Federal capital contribution needed in FY 1980 by $94 million.

--Reduction of Excess Cash in Direct Loan Program Institutional Revolving Funds: A tracking system has been developed and implemented to identify institutions participating in the Direct Loan program which are carrying excess cash in their revolving funds. These excess balances may occur because of lags between the receipt of funds by institutions and the disbursement of these funds to students for loans; or when loan collections exceed disbursements. New regulations will be implemented which require institutions to return excess funds so that other institutions can use the funds for student loans. These actions will enable the Office of Education to more effectively use existing resources and will reduce the need for Federal capital contributions.

The fraud and abuse activities are funded from the Office of Education's salaries and expenses account and the administrative set-aside for the student assistance programs and are an integral part of the total costs to administer the Office of Education's programs. Consequently, it is not possible to specifically isolate the cost elements for the fraud and abuse activities. However, we believe that the key to controlling fraud and abuse is effective management of the programs and practically all of the administrative funds for the student assistance programs are used for that purpose.

INDEPENDENT STUDENT LIBERALIZATIONS

Question: As you know, one of the final acts of the last Congress was approval of Middle-Income Student Assistance Act which, among other provisions, allowed students who are financially independent of their parents to qualify for at least as much assistance as dependent students. I understand that it is your position that language put in last year's appropriation bill delaying the effective date of the more liberal formula precludes the Department from assisting independent students in the coming academic year. Yet, it is the view of the Chairman and members of the Committee that subsequent law (the Middle-Income Act) takes precedence over prior law. What is the Department doing in this regard?

Answer: No formal opinion was issued by HEW General Counsel with regard to the FY 1979 appropriations bill limitations. However, HEW officials believe that an appropriations bill would take precedence over authorizing legislation regarding the use of appropriated funds.

The decision not to fund independent student liberalizations in FY 1979 was strictly a matter of budget policy and was not based on legal interpretations regarding the FY 1979 appropriations bill or the Middle-Income Student Assistance Act. Because of budget constraints, the funding of these liberalizations was deferred until FY 1980.

However, despite restrictions in last year's Labor-HEW bill on the use of 1979 appropriation for independent student liberalizations, these provisions could be funded from funds carried over from the FY 1978 appropriation for Basic Educational Opportunity Grants. In order to do this, it would be necessary for the Congress to waive the restriction that limits the carry-over to no more than 15 percent of the amount appropriated and to eliminate the requirement to provide full entitlement awards to students participating in the program during the 1978-79 academic year. Both of these would require legislative action.

In addition to the legislative changes, it would be necessary to amend the Family Contribution Schedule to reflect the appropriate treatment for independent students.

TITLE I, ELEMENTARY AND SECONDARY EDUCATION ACT

Question: The Education budget includes funds to implement the so-called urban-rural concentration program under Title I, Grants for the Disadvantaged. This new program is designed to assist school districts with large concentrations of disadvantaged students. For 1979, a $258 million supplemental is requested; $400 million is requested in 1980. This is the only major new initiative for education.

Why is this concentration program such a high priority of the Administration?

Answer: We are putting additional Title I dollars into concentration grants because we believe this provision will be the most effective method of focusing resources on areas with the greatest need.

Although the existing Title I program is making progress, districts with especially high concentrations of low-income students need special attention.

More intensive and costly remedial programs are required for low-achieving poverty children when they are found in large concentrations. A number of studies indicate that concentrations of poverty have a particularly negative effect on individual achievement.

For example, a national study by the Decima Research Corporation shows that low achievement among low-income children is substantially higher in big cities when compared with similar children in small cities.

According to another study, the Anchor Test Study, sponsored by the National Center for Education Statistics, students from high-poverty schools in urban and rural areas did less well than students from high-poverty schools in other communities.

Also, data on reading scores compiled by the National Assessment of Educational Progress show a disproportionate increase in low achieving children as poverty rises above 20 percent in both extreme rural and extreme inner-city schools.

These studies support the policy in the budget that additional Title I resources should be provided for concentration grants which target funds on the neediest counties.

Question: Isn't this program really another form of urban aid? (Note: About $256 million of the funds requested in 1980 would go to 11 predominantly urban States.)

Answer: The concentration provision is designed to target funds on both urban and rural counties with large numbers of poor children. It is true that a large amount of concentration funds would go to urban areas. However, poor rural counties will also receive more funds under the concentration provision than they would if the same amount of funds were allocated under the basic Title I formula.

We have looked at selected counties in several Southern States in order to compare how much Title I funds these counties would receive if the $400 million included in the 1980 request were allocated according to the concentration provision or according to the basic Title I formula. Based on this preliminary analysis, there are some good illustrations of poor rural counties which would benefit more under the concentration provision than under the basic Title I formula.

For example, Lowndes and Wilcox counties in Alabama; Breathitt, Knott, Magoffin, and Martin counties in Kentucky; Tensas and West Feliciana counties in Louisiana; and Braxton,

Calhoun, and Clay counties in West Virginia are rural counties which would receive a greater share of the $400 million under the concentration provision than under the regular Title I formula.

These are only examples. Our analysis was not intended to be a full survey of every county. But the important point is that the concentration formula is intended to target funds on the poorest counties, regardless of whether they are located in urban or rural areas.

COMPLAINT BACKLOG

Question: I note that the budget reduces funds for the Office of Civil Rights from $68 million to $65.6 million, with the explanation that OCR will have eliminated its backlog of complaints by the time the fiscal year begins. What is the current backlog of uninvestigated complaints?

Answer: As of January 31, 1979, the backlogged and carryover complaints were 1,060. As specified in the Adams Order over 50 percent of all backlogged and carryover complaints were closed prior to January 1, 1979.

REGULATIONS REVIEW

Question: Approximately what percentage of your regulations have been rewritten so far and when do you expect to complete the job?

Answer. HEW's goal is to review and rewrite approximately 2,000 pages of existing regulations in the Code of Federal Regulations by the end of March. HEW has already deleted 705 pages of obsolete and unnecessary regulations. This is 11 percent of HEW's regulations. HEW has finished rewriting 221 pages of its existing regulations in plain English. Another 426 pages will be in final form by the end of March or very soon thereafter. Another 1,237 pages will be in proposed form by the end of April.

HEW expects to complete the job of reviewing more than 6,000 pages of existing regulations under its five-year Operation Common Sense schedule (1977-1982). Of course, new or amended statutory requirements also add to the regulations workload. For example, the Education Amendments of 1978 added a number of new programs for which implementing regulations are now in preparation.

AUDIT STAFFING

Question: With respect to the level of authorized personnel in the Office of Assistant Inspector General for Auditing, is the current authorized level of 960 adequate to meet your responsibilities in this area?

Answer: The disparity between audit resources and audit workload continues to be an item of significant concern. Currently, we are authorized resources to perform approximately 72 percent of the audit effort necessary. As a consequence of this shortfall in staffing, we had to cut back on the audit frequency of smaller and medium sized institutions to less than prudent cycles, and further postpone covering areas that have received little or no recent audit attention. This situation was further strained since we needed to utilize nearly a quarter of Audit's in-house staff to carry out special Inspector General's initiatives during FY 1978. Currently, the Audit Agency's staffing situation is as follows:

		In Staff-Years
Total audit workload--based on several studies of high validity in recent years		4,554
Less: Resources		
Authorized in-house staff	960	
Staff-year equivalent of work performed by public accountants, States, others	2,332	3,292
Unmet audit needs		1,262

We are continually looking into ways to augment our audit capability. One of the most promising is the expanded use of contracts with non-Federal audit staff. During FY 1979 we were authorized $2.25 million for such contracts--the equivalent of about 60 staff-years of audit effort.

The budget now before the Congress proposes an additional 30 staff-years of contract support. We must stress though that this growth needs to be complemented by some growth in-house for planning, monitoring and supervision purposes. We believe such in-house growth in succeeding years should average at least ten percent annually--approximately 100 positions each for the next ten years. Although this is an optimal number, in consideration of serious budgetary restrictions a minimum of five percent annual growth rate is essential and appears a reasonable compromise at this time.

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Question: Is it true that these new regulations will result in increased paperwork and hardships on students because of increased tuition costs?

Answer: Tuition costs should not increase as the result of the January 25, 1979 regulations. These regulations changed the defiition of a payment period for institutions using clock-hours to measure progress. Many institutions which measure progress by clock-hours found that the previous calculation procedures which used months as the unit of measurement was not sufficiently flexible to accommodate students attending a program for varying numbers of hours per week. Thus, it is proposed that a payment period at clock-hour institutions would be made up of a fixed number of clock-hours. The second payment period would begin when the student completed the number of clock-hours comprising the first payment period.

When the exact fraction for enrollment status and the definition of a payment period are used, a student's Basic Grant payment is computed at clock-hour institutions using the following equation:

$$\text{Scheduled Basic Grant Award} \times \frac{\text{Number of credit or clock-hours the student is expected to take in a payment period}}{\text{the number of credit or clock-hours that a full time student would take in an academic year}} = \text{Basic Grant Payment for a Payment Period}$$

This revision in the method of computing awards for students in clock-hour institutions was adopted because it is more equitable for students, since it is computed on the basis of an exact reflection of their status as it relates to full-time status. Additionally, it was devised in response to concerns expressed by clock-hour institutions that the previous method of computation was too rigid for students enrolled in their programs which allow students to vary the number of hours per week that they attend school. If a student chooses to reduce the number of hours of attendance per week, his or her payment period will be extended in terms of calendar time, since the payment period is measured in hours which must be completed, just as the institution's program is measured in clock-hours.

This procedure does not result in any additional paper work for a student nor does it have any relevance to a student's tuition costs, since the tuition cost is for the program of study and the program is composed of a fixed number of hours.

BASIC GRANTS: REGULATIONS

Question: The January 25, 1979 Federal Register printed new regulations pertaining the refunds under the Basic Educational Opportunity Grants (BEOGs) program. The new regulations require institutions such as trade schools to base refunds for BEOGs on a clock-hour basis rather than on a monthly basis. The trade schools in Washington State say that these new regulations will create extra paperwork and a hardship on students due to the increase in tuition that will be required to implement them. One school says it has already raised tuition from $2,300 to $3,600 a year in order to comply with the regulations.

Can you please explain why these new regulations are being implemented?

Answer: The new regulations are being implemented primarily for two reasons as follows:

(1) To reflect more accurately the enrollment status of part-time students and to pay them accordingly.

(2) To provide a more realistic means of measuring a payment period at institutions that use clock hours to measure progress.

Question: Why are you requiring that refunds be calculated on a clock-hour basis?

Answer: The regulations published on January 29, 1979 did not include the formula for institutional refunds. In proposed regulations on institutional fiscal and administrative standards published on August 10, 1978, two possible refund formulas which would be used for all Title IV student assistance programs were submitted for public comment. At the present time, the Office of Education is studying the comments which were submitted on the August 10th proposed regulations and no final decision has yet been made on the formula for the final regulations. We expect, however, that the final regulations will be published and in effect by July 1, 1979.

Refunds on the basis of clock-hours that you refer to were probably proposed by the Federal Trade Commission (FTC). On December 28, 1978, the FTC issued final regulations regarding proprietary vocational and home-study schools. These rules set forth a refund policy based upon a clock-hour determination of the amount of tuition a student used before withdrawing from the school.

Chairman MAGNUSON. After the recess today, we will begin at 10 o'clock tomorrow with some health people.

Now, one other question. We put a limitation on your consultants cost last year. Has that been helpful?

Secretary CALIFANO. Mr. Chairman, as a result of your bringing the matter to my attention, I put in a rule about consultants. We put out a directive that puts a cap of 90 percent on appointive consultants. It permits the components of HEW to use only 90 percent of their consultant funds that they used last year. We will meet that.

I would much prefer to be relieved of the lid and to be permitted to do this administratively. But I would like to submit for the record the detail of what we have done, because I think it is pretty good.

[The information follows:]

REDUCTION IN APPOINTIVE CONSULTANTS

As far as appointive consultants are concerned, we imposed a 90 percent ceiling to prevent cost escalations until we develop reliable accounting systems which would enable us to control expenditures. We have now eliminated almost all the flaws in our computer programs and we will soon have accurate aggregated data we can use to monitor this category of consultants and their earnings. For other categories of consultants we are taking a number of steps in budgeting, planning, and auditing to manage the use of consultant services and control costs. For example, we are developiong new procedures which will utilize ZBB principles to determine the appropriate overall levels of proposed funding. In the area of evaluation, we are instituting planning procedures under the leadership of a newly created Deputy Assistant Secretary for Evaluation which will involve senior officials in determining the merits of proposed projects. We will also conduct special post audit reviews of a selected sample of all types of completed consultant projects to determine the degree to which the consultant has met objectives and has impacted on the performance of HEW programs. Through these measures, I believe we can get a firm grip on the management and cost of our consultant services and I therefore think that a legislated ceiling is not necessary.

Chairman MAGNUSON. Senator Schweiker would like his opening statement put in the record, and he has some questions to be answered for the record.

[The statement follows:]

STATEMENT OF SENATOR SCHWEIKER

Overview Hearing with HEW Secretary Califano

Mr. Secretary, I am glad to welcome you to this hearing. You've been a witness before this Subcommittee on a number of occasions and I have been glad to have you. This, of course, is my first year as the Ranking Minority Member of the Subcommittee.

The HEW budget request, on which we begin hearings today, is the biggest in history -- $61 billion just for the programs under the jurisdiction of our Subcommittee. And that does not even take into account the approximately $140 billion in trust fund expenditures over which this Committee exercises no direct control.

We recognize, of course, that HEW programs constitute some of the most sensitive activities of the Federal government: support for lifesaving biomedical research, provision of health care, education and social services to the nation's disadvantaged, and financial aid to children, the sick, aged, and disabled.

But the HEW budget has grown at an astounding - some would say alarming - rate. The public has become highly critical of such unchecked Federal spending and if anyone doubts that fact they should acquaint themselves with the number of states calling for a constitutional amendment requiring a balanced Federal budget.

I think the public is telling us to carefully examine the programs we do fund to make certain:

That they still are needed.
That they do what they are supposed to do.
That they aren't swamps of bureaucratic red tape.
And that they are devoid of fraud and abuse.

And I think the public wants us to be very careful about adding costly new programs that could better be done by state or local government, or the private sector.

In short, it is time to reassert control over the growth of the HEW budget.

We need to look not only at the proposed spending levels, but also at the efforts to achieve savings. For if these savings are not achieved, we will be faced with appropriating still more money later to make up the difference. Indeed, even as we sit here we are being called upon to provide a $1.6 billion supplemental appropriation, half of which covers shortages of funds for Medicaid payments, student loan defaults and the like.

We can't keep going on like this. We must be sensitive to human needs, but we must be prudent with the taxpayers' dollars. And above all we must insist upon

good, competent and watchful management by HEW and all of the agencies we oversee.

AUDIT RESOLUTION

Question: According to the General Accounting Office, as of their last review your Department had more than 2,000 unresolved audits involving in excess of $193 million. What is the current situation with your unresolved audits--how many are there and how long will it take to clear them up?

Answer: As of December 31, 1978, the total number of unresolved audits was 2,099 involving $230.6 million. The 2,099 reports included 920 that were over 6 months old. Since auditing is a continual process, a certain number of audits will always be unresolved at any given time. We are concerned, however, that the current level of unresolved audits is too high, and we are committed to reducing it. The operating component heads have been directed to take personal responsibility for ensuring that significant progress is made in this effort over the next quarter. We are also reviewing the procedures used by the operating components in resolving audit reports and will make changes as necessary.

OFFICE OF INVESTIGATIONS

Question: How do the functions of the Office of Program Integrity in HCFA differ from those of the Office of Assistant Inspector General for Investigations?

Answer: During 1977 it became clear that in the area of criminal fraud investigations both the Office of Investigations and the Office of Program Integrity, Health Care Financing Administration had been carrying out many similar functions. In order to more clearly define their roles and responsibilities, operating statements were prepared and new procedures were outlined. These new procedures include the orderly transfer of full responsibility for criminal investigations from HCFA's Office of Program Integrity to the Inspector General's Office of Investigations. The Program Integrity staff will concentrate on systems validation studies of State Medicaid Departments--and of Medicare intermediaries and carriers.

REGULATIONS REVIEW

Question: What is the current status of your effort to simplify HEW regulations?

Answer. HEW is nearing the end of its first 18-months of "Operation Common Sense." Operation Common Sense is a five year effort to review and, where necessary, revise all of the Department's regulations. These regulations currently fill over 6,000 pages in the Code of Federal Regulations (CFR). The goal of this review and revision is to produce timely, well-written regulations that do not impose unnecessary burdens on the public. By March 31, 1979 (the end of the first 18-months), HEW will be close to its initial goal of reviewing almost 2,000 pages of regulations (specific numbers are set out in the answer to the next question).

Regulations already rewritten are clearer, less burdensome, less detailed and reflect improved public participation in the regulations development process.

The complexity of many of the Department's regulations is in part a result of the statutory and adminstrative complexity of the programs HEW administers. Thus, HEW has had to work to simplify policies and procedures as well as to explain them in "plain English".

HEW has received favorable comments on a number of its revised regulations, including:

- Social Security regulations that concern evidence to prove eligibility for benefits, application for benefits, and who qualified for benefits under the Old-Age, Disability, Dependents' and Survivors' program;

- Regulations regarding State Plan requirements for the Medicaid, AFDC, child support enforcement, and social services programs; and

- Medicaid regulations (HEW has rewritten virtually all of the Medicaid regulations into plain English.)

HEW has also streamlined its internal regulations development process to ensure that new regulations are issued on a timely basis. In the past that has not always been the case. For example, it took HEW over three years to issue final regulations under section 504 of the Rehabilitation Act of 1973 (prohibiting discrimination against otherwise qualified handicapped individuals).

ASBESTOS IN SCHOOLS

Question: Has HEW made an assessment of the extent of the problem of asbestos in school buildings?

Answer: HEW has no general authority to assist the States and local school districts with assessing the numbers of school buildings constructed with asbestos-containing materials. However, in 1977 and 1978 the Department supported a study by Dr. William Nicholson of the Mt. Sinai School of Medicine of the Feasibility of the Control of Sprayed Asbestos Surfaces in School Buildings. This study, conducted in New Jersey, confirmed the presence of asbestos in 62 of 64 samples taken (New Jersey estimates 11% of their schools contain asbestos materials). This figure was based on the results of a request by the New Jersey Department of Education that school districts report the presence and condition of asbestos surfaces in all school buildings in the State.

Question: Do you have any estimates of the potential cost of correcting the problem?

Answer: Dr. Nicholson estimates the cost of sealing asbestos-containing materials will average $2 to $3 per square foot; the cost of removing and replacing these materials is estimated to average $5 to $7 per square foot, possibly ranging up to $10 per square foot.

Question: Do you plan to offer any proposals to deal with this situation?

Answer: The Public Health Service has advised me that any exposure probably carries some risk of disease, although it is not possible to estimate at the present time the risk from the levels of exposure observed in the schools. In May 1977 the Center for Disease Control notified all State health departments through HEW regional offices of the potential hazard of asbestos in schools and other public buildings. In that same year the New Jersey study was begun. In August of last year a letter was sent to State Governors alerting them to possible health hazards from asbestos exposure in schools and other public buildings. The Governors were encouraged to survey their schools for asbestos-containing materials and were offered technical assistance and informational resources of the Department. In this latter effort HEW is cooperating with the Environmental Protection Agency who has the primary responsibility for dealing with this situation. The Department's research institutes--NIEHS, NCI and NIOSH--are offering scientific support to EPA upon request.

The National Cancer Institute has planned a grant's demonstration program, which will focus on two aspects of the problem: (1) the health education of students and school personnel, and the education of contractors and construction workers involved in the removal or sealing of asbestos materials; (2) the development of a management approach for organizing the removal or sealing of the asbestos material which can be applied to other school systems. NCI plans to commit approximately $2,000,000 to this program in 1980.

VOCATIONAL EDUCATION

Question: In last year's appeal letter to this Committee you said that recent evaluation reports raise questions about the effectiveness of the Vocational Education program. You pointed out that the data indicate that Vocational Education students are no better off in the labor market than students in non-vocational schools, and that States now spend $11 dollars for every Federal dollar. If this is the case, why have you not recommended a reduction in the level of Federal support in FY 80 for this program? Wouldn't our money be better spent elsewhere?

Answer: All of my comments last year were made as part of an argument against a proposed Congressional increase in the President's request for Vocational Education. Because of the substantial overmatching of Federal Vocational Education dollars by the States, I felt vocational program needs could be met without increasing Federal funds. This is still our position in 1980: we are asking you to hold Federal Vocational Education funds level. We have recognized the final appropriation for 1979, which did exceed our budget request, but we are asking you to stay at this level in 1980.

VOLUNTARY COST CONTROLS

Question: What steps have you taken to encourage the success of the voluntary effort to control hospital costs -- which might eliminate the need for Federal regulatory controls on hospitals?

Answer: HEW believes that the hospital industry will successfully meet the President's voluntary guidelines of 9.7 percent in 1979. Preliminary figures indicate that the hospitals have made an encouraging start: the rise in hospital expenditures in calendar 1978 was down to 12.8 percent, compared to 15.6 percent the year before.

We want to give the nation's hospitals the opportunity to meet the national voluntary limit contained in the Administration's Hospital Cost Containment Legislation. In an effort to be reasonable, our legislation stipulates that hospitals will be guaranteed an inflation allowance based on the increase in the cost of the goods and services they must buy, even if the actual inflation rate turns out to be greater than the 9.7 percent which is currently projected. Finally, the Department believes that the voluntary effort will be more likely to succeed because hospitals will want to avoid triggering the standby mandatory program.

SEX DISCRIMINATION PROHIBITIONS

Question. You have proposed a plan for enforcing Title IX prohibitions against sex discrimination in collegiate sports. What are the major provisions of this plan?

Answer: The plan for enforcing Title IX prohibitions against sex discrimination in collegiate sports consists of two major components. First, it is designed to eliminate discrimination in existing programs. Second, it is designed to ensure, in a broader perspective, that the interests and abilities of women are equally accommodated.

To ensure that intercollegiate athletic programs at colleges and universities provide equal opportunities for both sexes, the plan provides that an institution's average per capita expenditures for male and female athletes on financially measurable benefits, (e.g. financial assistance, recruiting, and others) are substantially equal. Similarly, it provides for comparability in benefits and opportunities that are not financially measurable. These include: opportunity to compete and practice; opportunity to receive coaching and academic tutoring; provision of locker rooms, practice and competitive facilities; provision of medical and training services and facilities; and provision of housing and dining services and facilities.

To ensure that the interests and abilities of male and female students are met, the plan requires that colleges and universities follow institutional policies that include procedures and standards for developing athletic programs that meet these interests and abilities. Both parts of the plan must be satisfied in order for an institution to be presumed in compliance with Title IX.

Question: Have you modified it on the basis of public comment?

Answer: The Office of Civil Rights extended its deadline for receiving comments from February 10, 1979 to March 2, 1979 which allowed the public more time to comment. OCR received 637 comments from across the country and from varied interested parties. Basically the comments have been mixed, however, overall the comments are favorable to the type of approaches outlined in the plan. Presently, OCR is determining and preparing appropriate modifications to the plan based upon the comments received from the public.

Question. Will this plan add substantially to the enforcement responsibilities of your Office of Civil Rights?

Answer: Since the Office of Civil Rights already has responsibilities for enforcement of Title IX, there is no increase in enforcement responsibilities. In fact, by providing specific policy guidance on this issue, enforcement of this portion of the Title IX regulation will have been greatly facilitated.

NATIONAL HEALTH INSURANCE PLAN COST

Question: Mr. Secretary, I understand the Department has committed considerable new resources to the development of a National Health Insurance recommendation, and also to compiling a vast amount of background information on the subject. Do you have any estimates on how much this has cost the taxpayers? Would you supply the Subcommittee with a breakdown of these expenditures?

Answer: From 1977 through 1980, the Department will have committed $4.4 million toward the development of this Administration's National Health Plan proposal. This effort has involved a thorough analysis of alternative proposals - ranging from the most basic to the most comprehensive - and of the potential cost and impact of each alternative on various sectors of the economy. A substantial proportion of this effort has gone into refining our ability to model National Health Insurance options and providing quick estimates. We have also developed models to estimate the impact of various plans on taxpayers at varying income levels and to assess the impact of a health plan on the economy.

We have also invested our resources in the most comprehensive effort in recent memory to seek the views and recommendations of the American public on this issue:

- The National Advisory Committee on National Health Insurance held hearings throughout the country in 1977 and 1978, to which representatives of the entire spectrum of health care interests were invited to present their views and recommendations;

- Similar hearings were conducted by our Regional Offices in over 100 communities during the latter part of 1977 involving more than 8,000 individuals from all walks of life who attended as speakers or submitted written statements on National Health Insurance issues;

- I have personally spent a considerable amount of my time meeting with members of Congress and health industry representatives in an earnest exchange of ideas and opinions on this subject.

I consider this to be a worthwhile investment because it has provided us with a wealth of valuable information on what Americans need and expect from a National Health Insurance Plan.

Our current plans call for submission of the Administration's National Health Plan proposal by early summer. We anticipate that Congressional hearings on the subject will be scheduled soon thereafter. Most of our efforts over the next two years will be directed toward providing necessary information to the Congress - on the Administration's plan and on other proposals actively considered - in order to assist in the public and Congressional debates on National Health Insurance. We will focus particularly on refining our data on the cost and health effects of the alternative proposals under consideration.

COST CONTAINMENT

Question: You have projected savings of $1.7 billion in Medicare and Medicaid in 1980 resulting from hospital cost containment legislation. What kind of legislation are you considering that would achieve this savings?

Answer: The proposed hospital cost containment legislation will result in fiscal year 1980 savings of $1.4 billion. The $1.7 billion savings will result if the hospitals follow the President's anti-inflation guidelines. Under the legislation a mandatory limit, set approximately equal to the rate of inflation in the hospital's market basket, will be set on inpatient revenues per admission for each hospital under the mandatory program.

Hospitals are exempt from the mandatory program if they: are in States with approved mandatory cost control programs; are in States which meet the voluntary limit; individually meet the voluntary limit; or are a small non-metropolitan hospital.

Question: Will this legislation be more restrictive than the plan you backed last year?

Answer: The proposed legislation is more precise than last year's proposal because it is more tailored to the individual hospital. Therefore, even though the rate of increase in total hospital revenues may be lower than it would have been under last year's proposal, I am confident that it is more equitable.

Question: What level of inflation in the general economy and in the so-called hospital market basket have you assumed in calculating this savings?

Answer: The general rate of inflation is actually not relevant in determining the hospital's market basket inflation. Each item in the hospital's market basket is given its own rate of inflation. The inflation index varies from 1.5 percent for apparel to 15 percent for malpractice insurance costs.

TOTAL HEW BUDGET REQUEST

Chairman MAGNUSON. Now, I have a bottom line for you: How much is the total HEW budget?

Secretary CALIFANO. From this subcommittee?

Chairman MAGNUSON. Yes.

Secretary CALIFANO. $60.8 or $61.3 billion if you include the new legislation.

Chairman MAGNUSON. Leave the new legislation out. If we marked up the bill tomorrow, how much would you ask for?

Secretary CALIFANO. $60.8 billion.

Chairman MAGNUSON. How does that compare with last year, last year's outlays?

Secretary CALIFANO. In fiscal 1979 the appropriated amount is $58.1 billion, but what we actually think we're going to have to spend is $59.5 billion. We think we're going to need more money for medicaid than was appropriated for last year.

Chairman MAGNUSON. Now, that's an estimate.

Secretary CALIFANO. On both our parts. The year before last, you were clearly right. I think this year it may be higher and we will need a little extra money.

Chairman MAGNUSON. We hope it isn't.

Secretary CALIFANO. So do I.

INCREASED EXPENDITURES

Chairman MAGNUSON. Are you over last year's expenditures?

Secretary CALIFANO. Very gently, Mr. Chairman.

Chairman MAGNUSON. How much?

Secretary CALIFANO. Well, in terms of what is appropriated, from $58.1 to $60.8 billion, only $2.7 billion and 4 percent, and in a time that inflation is predicted to run about 9 percent.

Chairman MAGNUSON. That's the first admission we've had from the administration.

Secretary CALIFANO. That is not the OMB projection. I would retract that. [Laughter.]

Chairman MAGNUSON. But anyway, in round figures, you are pretty close to asking the Congress for just about what you had last year.

Secretary CALIFANO. Yes, sir. Indeed, we could not be here with that request if we didn't have a lot of the management improvements we have had in the last several years. We are really saving.

Chairman MAGNUSON. You believe you've done a good job on that, and if that hadn't been done and things went along the way they were going you would have to ask for much more than this amount?

Secretary CALIFANO. We would, Mr. Chairman.

Chairman MAGNUSON. Do you have any estimate on how much?

Secretary CALIFANO. By 1980, maybe $2 billion more.

Chairman MAGNUSON. All right, then. You can answer the further questions I had.

And Senator Eagleton, you've been very patient.

OFFICE OF INSPECTOR GENERAL

Senator EAGLETON. Thank you, Mr. Chairman.

On this question of costsavings, Mr. Secretary—and I think you have instituted many new systems that are in fact saving considerable amounts of money. I am a bit disappointed, though, in your budget request for the Office of Inspector General. I have to think that money invested in those funds just reaps enormous dividends, and you are holding level the number of permanent positions in the Office of Inspector General.

Now, bearing in mind that you are responsible to audit, I think, something like 50,000 institutions, how can 1,244 employees begin to audit 50,000 institutions?

Secretary CALIFANO. They can't, Senator. What they will have to do is audit some of them on a spot basis. This raises a question that I think we should all think about, which is whether we shouldn't begin to make a distinction between personnel or money invested that returns more than the money we invest, rather than just counting everybody the same way. An auditor, for example, might produce $1 million with his $20,000 salary.

Senator EAGLETON. The IRS in their budget submission before another subcommittee, they are pretty good with figures. You're good with your charts. They're good with their charts, too, in proving that for so many extra IRS agents, that brings in so many more millions of dollars. Now, I forget what the cost-benefit ratio is, but according to their figures it is substantial. And I think the same would be generally true in the Office of Inspector General.

Secretary CALIFANO. Well, I tried that with OMB and, since I could not get the charts out of them, I can't bring them over and show them to you.

ARCHITECTURAL BARRIERS TO THE HANDICAPPED

Senator EAGLETON. Now, we talked briefly about the handicapped in answer to an earlier question from Senator Magnuson.

Last year, the Senate report that accompanied the fiscal year 1979 appropriation bill directed the Department to report to the committee by last November 30 on the cost of removing architectural barriers for all institutions affected by section 504 of the Rehabilitation Act, and a more precise definition of what is meant by, "accessible to the handicapped."

How is this report coming along?

Secretary CALIFANO. Senator, we are a little behind. We hope to have the report by April or thereabouts. Part of it is our delay and part of it is due to the difficulty in getting this information from the universities and verifying it at least on a spot basis, because the natural inclination is to look for the most expensive way.

We should make it by April.

Senator EAGLETON. We hear—although you discount it—we hear grandiose figure estimates of what this might cost: very large figures, in the tens and hundreds of millions, and even in the billions now.

You feel that those are considerably exaggerated, I take it?

Secretary CALIFANO. I do, Senator. The reason I held those regulations up, and the fundamental change I made in those regulations before issuing them, was to make it a point of program accessibility and not to make every room in the building accessible. Now, that can solve a lot of problems.

I'm sure there are some burdens in terms of scheduling classes on occasion, and we can't solve the problems in the laboratories, where you have to actually move the equipment, and you have to have certain standards of air ventilation for safety and so on.

Senator EAGLETON. That's all I have, Mr. Chairman. Thank you.

Thank you, Mr. Secretary.

SUBCOMMITTEE RECESS

Chairman MAGNUSON. We will recess the subcommittee and begin tomorrow with the health programs.

Secretary CALIFANO. Mr. Chairman, thank you.

[Whereupon, at 4:25 p.m., Monday, February 26, the subcommittee was recessed, to reconvene at 10 a.m., on Tuesday, February 27.]

DEPARTMENTS OF LABOR AND HEALTH, EDUCATION, AND WELFARE AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 1980

TUESDAY, FEBRUARY 27, 1979

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
Washington, D.C.

The subcommittee met at 10 a.m. in room S–128 of the Capitol, Senators Charles McC Mathias, Jr., and Lawton Chiles presiding.
Present: Senators Chiles, Mathias, and Schweiker.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

HEALTH SERVICES ADMINISTRATION

STATEMENT OF DR. GEORGE I. LYTHCOTT, ADMINISTRATOR

ACCOMPANIED BY:
DR. EDWARD D. MARTIN, DIRECTOR, BUREAU OF COMMUNITY HEALTH SERVICES
DR. JAMES H. ERICKSON, DIRECTOR, BUREAU OF MEDICAL SERVICES
LA VARNE TAYLOR, DIRECTOR, OFFICE OF FINANCIAL MANAGEMENT
BRUCE S. WOLFF, ACTING DEPUTY ASSISTANT SECRETARY FOR LEGISLATION
WILFORD J. FORBUSH, DEPUTY ASSISTANT SECRETARY, BUDGET

1979 APPROPRIATION AND 1980 BUDGET REQUEST

Senator MATHIAS [presiding]. The meeting will come to order.
The Chair wants to apologize to the witnesses for the delay, but I will give you a comforting and consoling fact for the long wait.
As we go through the budget process, you will receive a great deal of criticism for the way you run your individual shops and agencies and offices. And the fact that Congress schedules two meetings for the same hour at different places on different subjects should be some indication to you that Congress also makes mistakes.
It doesn't run its affairs as efficiently as it should.
And so that when you suffer the slings and arrows and barbs that will be thrown at you, you can at least take comfort in the fact that they don't come from an infallible source.
Now, Dr. George Lythcott, the administrator of the Health Services Administration, is with us this morning to discuss many of his

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programs and the fiscal year 1980 President's budget request made by President Carter.

We will also be discussing the supplemental request made by the President for fiscal year 1979 as well.

Totally, the President is requesting $1,370,897,000 for the Health Services Administration.

You see how you get accustomed to reading those figures smoothly as a member of this committee.

This is an increase of approximately $14 million over the amount requested and provided for in fiscal 1979. And I hope during your testimony, Doctor, you will advise us whether that $14 million increase is a constant dollar increase or a constant dollar decrease.

I think the committee is interested in just where we are as compared to last year in real terms.

However, there is a lot of—I hesitate to use the word juggle because that has a connotation to it, but the figures are somewhat transposed and I think we will look forward to discussing this in some detail with you and your colleagues. At that point, you perhaps might wish to introduce those who are with you for the record.

Dr. LYTHCOTT. Senator Mathias, I would like to introduce for the record Dr. Edward D. Martin, Director, Bureau of Community Health Services.

On his left, Dr. James H. Erickson, Director, Bureau of Medical Services; on my right, Ms. LaVarne Taylor, Director, Office of Financial Management, Health Services Administration; and on her right, Mr. Bruce S. Wolff, Acting Deputy Assistant Secretary for Legislation; and on his right, Mr. Wilford J. Forbush, Deputy Assistant Secretary, Budget.

Senator MATHIAS. Dr. Lythcott, we have your prepared statement, which will be submitted in full in the record as if read. And the committee has the benefit of your views through that statement.

Perhaps you would like to summarize it very briefly and then we can go straight to the questions.

[The statement follows:]

STATEMENT OF DR. GEORGE I. LYTHCOTT

Mr. Chairman and Members of the Committee:

I am pleased to have this opportunity to discuss with you the Health Services Administration budget request for fiscal year 1980.

The importance of the programs administered by the Health Services Administration continues to increase. In a period of fiscal restraint, the programs of the Health Services Administration not only provide a source of funds for health services to the medically indigent inner-city and rural populations, but also provide leadership, technical assistance and management expertise to enhance the quality of health care services and the efficiency with which they are provided. In addition, the Health Services Administration continues to provide direct delivery of health care to Federal beneficiaries through the PHS Hospital and Clinic System and through the Indian Health Service. As you know, however, the budget request for the Indian Health Service is considered by the Department of the Interior and Related Agencies Subcommittee. The Health Services request now before you is for the Bureau of Community Health Services, the Bureau of Medical Services and the Office of the Administrator, all within the Health Services Administration.

For fiscal year 1980, we are requesting $1.4 billion for the Health Services programs. This request contains significant increases for specific programs which focus on bringing health care resources into medically underserved and health care manpower shortage areas and which strengthen efforts to prevent illness. The beneficiaries of these programs include the residents of poor and remote rural areas, inner city residents and migrants.

I would like to add that, in conjunction with the fiscal year 1980 budget request, the Health Services Administration is requesting a supplemental of $100.2 million in fiscal year 1979. The funds requested are for programs which were not considered by the Congress due to a lack of authorizing legislation and thus were covered by the Continuing Resolution. The amount requested will be used to carry out the Inner-City and Adolescent Health Initiatives, to fully fund the National Health Service Corps, and to continue funding for the Sickle Cell Screening program.

In 1980, we are requesting $1.1 billion for the Bureau of Community Health Services. This request will permit us to continue efforts to build, expand and maintain service delivery capacity for medically underserved populations and to focus special attention upon the need for a child health initiative. Specifically, the Bureau of Community Health Services will continue to expand its ongoing activities to provide primary medical care in underserved areas. In fiscal year 1980, we are requesting $388.5 for the Community Health Centers program to

support 965 projects in urban and rural medically underserved areas. When fully operational, these projects will provide access to health care for an estimated 5.6 million people. This request includes an increase of $30 million, which will support 34 new rural centers and 11 new inner-city projects. This increase will establish a service capacity for an additional 203,500 medically underserved people. Within this total, we are continuing activities initiated in 1979 to provide comprehensive diagnosis and treatment to persons with Black Lung Disease.

Health Underserved Rural Areas projects funded in fiscal year 1979 will be continued in fiscal year 1980. However, about 46 projects costing $5.9 million will be funded under the Community Health Centers authorization. This is being done to comply with the provision in the authorization for Health Underserved Rural Areas which stipulates that only those projects which cannot be funded under other authorities should be funded under the Health Underserved Rural Areas authority.

Another critical goal of the Bureau of Community Health Services is improving the delivery of health services in the country's designated health manpower shortage areas, and reducing the number of such areas by the appropriate placement of health professionals and resources. For the National Health Service Corps, which serves as the principal means for carrying out this goal, the fiscal year 1980 request is $81.8 million. This funding level will support the placement of 2,820 health professionals, an increase of 1,095 over the fiscal year 1979 level. These assignees will provide health services to an estimated 1.9 million people in 1,036 rural and urban communities.

The budget request for the Maternal and Child Health Grants to States program contains an increase of $11.9 million to implement a child health initiative in 1980. These funds will be used to establish six new types of discretionary grants in the areas of school health, newborn screening, accident prevention, immunization tracking and outreach services for mothers and infants. Approximately 87 grants will be made to State agencies in support of the child health initiative.

In addition, the fiscal year 1980 budget request includes $41.4 million for comprehensive health care services to migrants and seasonal farmworkers. This request represents a $6.9 million increase over fiscal year 1979. These funds will provide comprehensive health services for an estimated 590,000 persons in 112 existing centers, an increase of 33,000 people over fiscal year 1979. This represents approximately 22 percent of the estimated 2.7 million migrants and seasonal farmworkers and their family members.

We are requesting a $2.3 million increase for the Hypertension program. In 1980, $13.3 million will be awarded to State health authorities to assist them in providing screening,

detection, diagnosis, prevention, referral for treatment for hypertension and follow-up to assure that hypertensive patients are following prescribed medical treatments. Beginning in fiscal year 1980, this assistance to the States will be provided through project grants. This method will require States to be more accountable for program results and fiscal expenditures. Also, a more effective planning, organizing and management of the program will occur since resources can now be targeted to areas of greatest need for greater effectiveness.

For the Bureau of Medical Services we are requesting $220.4 million in fiscal year 1980, including $166.4 million for the operation of the PHS Hospitals and Clinics and $3 million to renovate patient dormitories at the Carville Hansen's Disease Center. The funds requested will be sufficient to maintain the PHS hospitals in compliance with Public Law 93-155. As you know, the Advisory Committee on the PHS Hospitals made its report last summer. A task force has been established within the Public Health Service to determine the best means for implementing the Committee's recommendations and is now at work. However, since the task force had not completed its analyses prior to the development of the fiscal year 1980 budget request, we are requesting sufficient funds to maintain the PHS hospitals at a level in compliance with the law until the implementation plan is completed.

The fiscal year 1980 request for the Emergency Medical Services program is $39.6 million and also will be sufficient for maintenance of the fiscal year 1979 level. This program has successfully demonstrated that through regional cooperation and coordination of local resources, effective emergency medical systems can be developed. Therefore, legislation is being submitted which calls for the phase out of the Emergency Medical Services program by the end of fiscal year 1982.

Finally, we are not requesting funds for the Burn program in fiscal year 1980 and are not proposing that the legislative authorization be extended. Funds which have been appropriated in prior years for the Burn program are being used to collect data on the incidence and treatment of burn injuries, and will be used to evaluate the need for a future Burn program. Therefore, we believe that it would be premature to make any such request at this time. A report containing analyses and recommendations based on the data now being collected will be presented to the Congress.

In summary, Mr. Chairman, I have described to you the very important initiatives contained in the Health Services fiscal year 1980 budget. The program increases for Community Health Centers, the National Health Service Corps, Migrant Health, Maternal and Child Health and Hypertension will do much to expand the availability of primary and preventive health care services to those most in need.

At this time, Mr. Chairman, I shall be pleased to answer any questions which the Committee may have.

QUALITY HEALTH CARE SERVICES

Dr. LYTHCOTT. Thank you.

I am grateful for this opportunity to discuss with you both our fiscal year 1979 supplemental and the fiscal year 1980 budget request for the Health Services Administration.

The principal mission of the programs administered by the Health Services Administration continues to be the provision of quality health care services to the medically indigent inner-city and rural residents, as well as Federal beneficiaries served through the PHS Hospital and Clinic System.

For 1979, we are requesting a supplemental of $100.2 million to carry out the innercity and adolescent health initiatives, to fully fund the National Health Service Corps, and to continue funding for the sickle cell screening program. This supplemental request will provide health care services to almost 600,000 additional urban and rural residents.

Included in our fiscal year 1980 budget is $1.1 billion for the Bureau of Community Health Services. This request will permit us to continue efforts to build, expand, and maintain service delivery capacity for medically underserved populations and to focus special attention upon the need for a child health initiative.

Through the combined efforts of the programs in the Bureau of Community Health Services, including 965 urban and rural community health centers and 2,820 National Health Service Corps assignees stationed in 1,036 manpower shortage area sites, the establishment of six new types of discretionary grants in the areas of school, medical, and dental health, newborn screening, accident prevention, immunization tracking, and outreach services for mothers and infants, and the expansion of the migrant and hypertension programs, quality health care services will be provided to approximately 23.1 million people in fiscal year 1980. This is 1.7 million more people than were served in 1979.

For fiscal year 1980, our budget request contains $220.4 million for the Bureau of Medical Services. This request includes $166.4 million for the operation of the PHS hospitals and clinics. This request will be sufficient to maintain the PHS hospitals in compliance with Public Law 93-155. In addition, our budget request includes $39.6 million for the emergency medical services systems program. This program has successfully demonstrated that, through regional cooperation and coordination of local resources, effective emergency medical systems can be developed. Since we now feel that this demonstration activity has fulfilled its objective, legislation is being submitted calling for the phaseout of the emergency medical services systems program by the end of fiscal year 1982.

Mr. Chairman, I have briefly summarized for you the major components in our 1979 supplemental and 1980 budget request.

At this time, I shall be pleased to answer any questions.

GAO STUDY OF COMMUNITY HEALTH CENTERS

Senator MATHIAS. Thank you very much, Doctor.

Last summer, the General Accounting Office made a report on neighborhood health centers, which includes some discouraging findings.

Now, you have just given us the numbers of these health centers. I think it should be noted that the GAO study only reviewed activities of six of those health centers, a sampling.

The committee takes note of the fact that it is dealing with a sampling. They found, however, that centers were overstaffed for the number of patients being treated, and that unnecessary costs have been experienced because anticipated patient demand had not materialized. And that the staff had not been reduced to the levels that were consistent with the demand.

Now in view of the very strenuous efforts made both by the legislative and executive branches, could you tell us why your department has been continuing the operation at an inefficient level, or what is judged inefficient by GAO?

Dr. LYTHCOTT. First of all, only six of our health centers were reviewed. And the important thing about the six is that four of the six were old OEO projects. And if you will remember, the OEO projects were intended to provide both employment and health care.

Senator MATHIAS. Now, so we are sure we are on the same track, we are talking about the 1978 report.

Dr. MARTIN. There was a 1978 report. The data they were using was from 1975 and 1976. It took them 3 years to write a report, so the data was already 3 years old.

They were audited in 1975 and 1976. We might add that four of those centers had already been scheduled for termination, and five had their boards changed.

So they selected six problem centers. And I think what we are doing now has resulted in improvements in these.

Senator MATHIAS. So they are not randomly selected?

Dr. MARTIN. It is statistically impossible with 167 centers to pick 6 of the 9 worst centers in the Nation to study, and indeed, that is what happened.

Dr. LYTHCOTT. I think also that the need for additional centers still exists. In answer to the second part of your question, the statistical CHC user is mostly employed below the $6,000 income level.

At the end of fiscal year 1980, including the present budget, we shall have 5.6 million people being served. Actually, 49.1 million people in need are out there. Therefore there is a continuing substantial need for additional service capacity.

I think it is important to say that through our systems, we have created a mechanism that is very effective. We have these centers working at a minimum administrative cost, and that is a standard of 20 percent for administrative overhead.

And I would add, if they do not meet that percentage figure, they are penalized. I am putting these accomplishments on the record because you will not find them in the GAO report.

Senator MATHIAS. So what you are telling us is that you have actually terminated some of the six centers.

Dr. MARTIN. Four of the centers were given to us to manage from the OEO program. They were terminated from the previous grant-

ees and changed over totally to new grantees. Three of the centers got new directors, and all of them were in the process of very intensive technical assistance.

As of now, five of the six centers are in compliance with the indicators that Dr. Lythcott indicated; there is one of the six still in difficulty.

The staffing ratios are consistent with the model and in that year the physician encounter ratio is above 4,000 per year. So that those centers which were, in fact, among the worst have now been brought to a point in the last 3 years where now many of the problems have been resolved.

Senator MATHIAS. And so you have made a determination that geographically, they are still necessary in the present location.

Dr. MARTIN. Yes.

Senator MATHIAS. Could you identify—you don't have to take time to do it now, but could you identify the locations of the designations of these six centers?

Dr. LYTHCOTT. Yes.

[The information follows:]

Location of the six centers reviewed by GAO

Name of Center	*Location*
North East Neighborhood Association	New York City, N.Y.
South Brooklyn Health Center	Brooklyn, N.Y.
Primary Health Care Corporation (Homewood-Brushton).	Pittsburgh, Pa.
Cleveland Neighborhood Health Services Inc. (Hough-Norwood).	Cleveland, Ohio
Mission Area Health Association	San Francisco, Calif.
West Oakland Health Council Inc.	Oakland, Calif.

COMPREHENSIVE HEALTH GRANTS TO STATES

Senator MATHIAS. Now, one of the biggest budget reductions for the fiscal year is the comprehensive health grants to States.

Of course, we've heard very promptly from the State health officials because of this proposed reduction.

Could you tell us why you are reducing the program and why you propose that all of the 63 positions in that category should be eliminated?

Dr. LYTHCOTT. Actually, that reduction, sir, is more apparent than real. We made the move in the first place to be——

Senator MATHIAS. It is very apparent to the State people, let me tell you.

Dr. LYTHCOTT. We made the decision so we could target the dollars that were going into the States. I think we can appreciate that the need in health will vary from State to State, and it will vary within a State.

When one targets funds of this nature, he is able to zero in on the areas that need help most.

Actually, we still are going to look into those things that are most important in terms of need: maternal and child health, dental treatment, and general health services.

However, the reduction that you speak about is a reduction in untargeted moneys.

Through the increases, on the other hand, in the maternal and child health care for the United States, in CDC prevention plans and mental health grants, it turns out that the reduction is about 4 percent.

The States are receiving $86 million in 1980 instead of the $90 million which they received last year.

So there's actually 4 percent less income than previously, but I think we are miles ahead in terms of being able to target the funds to areas where we need the money most.

Senator MATHIAS. What you are really telling me is that of the $38 million reduction in the program, other categories of programs through the whole Public Health Service are going to pick up the projects which otherwise would have been financed through 314(d).

Is that right?

Dr. LYTHCOTT. The activities, sir, not the project.

Senator MATHIAS. I think I said 63 positions that are being eliminated.

Dr. LYTHCOTT. Well, the need for those positions will not exist if we move into the target area.

Senator MATHIAS. We are having an interesting phenomenon here. You are talking about $52 million, but nobody to spend it.

Dr. LYTHCOTT. The people are assigned to the States and the States have the money. They will pick those people up.

Senator MATHIAS. They are State officials spending Federal money.

Dr. MARTIN. 314(d) money is given in the form of unrestricted revenue-sharing grants to the States. It goes directly to the State.

Those 63 positions were positions that the grantee got instead of grant funds. They were assigned to the States and they were used, for all practical purposes, as State staff.

In addition, there are thousands of other State staff. Indeed, 63 individuals and/or functions will be picked up by the States with the other employees who are basically working on these activities, anyway.

The 63 positions were a very tiny portion of the State staff administrating these activities. Instead of having Federal employees transferred to the States, then employed by the State, the Department thought it more reasonable just to have the States themselves hire the staff.

Senator MATHIAS. Who's going to have the public responsibility for this?

Dr. MARTIN. Under 314(d), States are unrestricted. There are no requirements for accountability except for those administered by the State health authorities. That would continue as it has in the past. That is, essentially, unrestricted moneys to the State health agency.

COMPREHENSIVE HEALTH GRANTS TO STATES—63 POSITIONS

Senator MATHIAS. Let me ask if my staff understands that.

[Discussion off the record.]

Dr. MARTIN. Previously, the dollars used for those 63 positions resulted in a reduction of cash available to the State. With the elimination of the positions, the availability of funds to the States

will increase. Therefore, the total amount of dollars being expended, including earmarkings, will remain about the same; it will all wash out.

Senator MATHIAS. Well, now, you state it is going to wash out. Let's take a hypothetical case.

Let's take California. Governor Brown wants to balance the Federal budget. And so we are going to cut back on Federal moneys and California will get less now out of the program, right?

Dr. MARTIN. Yes, sir. It will get less out of the unrestricted money. However, the State also will get hypertension, prevention, and mental health moneys.

Senator MATHIAS. But he will also then have to pick up the administrative personnel out of the State budget.

Dr. MARTIN. Most of whom he already pays for. And there are hundreds of people administering the 314(d) grant, of whom only 63 are these individuals paid by the Federal Government.

So it is an anomaly, having Federal employees to administer those State programs.

And this represents a small portion of the total employment within the State program.

Senator MATHIAS. You can understand why I was tempted to use the word "juggling" the funds.

Dr. MARTIN. We just feel that State employees who are carrying out State functions ought to be paid by the State instead of being paid by the Federal Government, essentially through the back door.

Senator MATHIAS. But where does this committee have oversight authority in the expenditure of these Federal funds?

Where do you, as Federal officials, have executive control over the funds?

Dr. MARTIN. We have no control whatsoever over the expenditure of these funds.

By law, the State must submit an application for funds which is not required to be approved and the State exercises complete authority over those funds.

And it is the single grant program in the agency over which we have no control. And given that, it was the judgment of the Department that 314(d) is reasonably described as a State unrestricted program.

Therefore, the 63 persons ought to be State employees.

HYPERTENSION

Senator MATHIAS. Well, let's pass on from that. We may have further questions about that as we review this record.

You're asking $13.26 million for the hypertension program and physical aid, but you also have a request for funding for the hypertension program of the National Heart, Lung, and Blood Institute.

Is there an overlap there?

Dr. LYTHCOTT. No, we work hand and glove with the NIH program and we meet on a regular basis.

They represent the education resources side of this effort and we are the screening side.

We clearly do not work against each other; we actually work in concert. We work together in the revision and the development of programs. It is very clearly a complementary relationship.

Senator MATHIAS. You say complementary. Could the two programs be folded together?

Dr. LYTHCOTT. I don't think so. We recognize them for what they do very well, and I hope they recognize us for what we do very well.

Senator MATHIAS. And there is no way to save the administrative costs that lay on top of each program?

Dr. LYTHCOTT. I don't believe so, sir. I don't think it would be worth that to run the jeopardy of having the program be less successful.

Senator MATHIAS. With the additional $2.3 million that you requested for fiscal aid, how many people would you be able to screen?

Dr. LYTHCOTT. By that time, by the end of 1979, we would be screening 3.8 million persons yearly and we will have picked up 119,000 newly diagnosed cases.

The number of persons screened range from 845 in Wyoming to 120,000 in Georgia, for example.

Dr. MARTIN. The 3.8 million persons screened is the latest information we have. An additional 1.4 million people will be screened with the 1980 budget level—this will bring the total in 1980 to 5.2 million screenings.

There will be new people screened all the time, so it is an active program to reassess for hypertension.

MCH GRANT TO STATES

Senator MATHIAS. Well, I certainly support this program very strongly. It is one of the critical health programs and health maintenance programs in the country.

I think we want to support it as adequately as it demands. I don't think we want to waste money on administrative costs that are associated with it, if we can avoid it.

Let me turn to another program in which I have great personal interest. I think it is one of the best investments for the future that we can have, because in terms of prevention, every dollar you spend today ought to save you, not $1 in the future, but $2 or $3 or $4 or $5 somewhere in the future.

And that program is the maternal and child health grants to the States for which you are increasing—you are requesting an increase in the amount of $12 million.

Now we ought to rejoice in the amount of that increase. But if you apply the constant dollar measurement, you are actually falling short for the coming year.

I think $12 million is less than half of the amount required to cover the cost of the inflationary increase.

Now who's going to suffer as a result of what is in fact a constant dollar, a real dollar decrease in the budget request for this program?

Dr. LYTHCOTT. I don't think anybody is going to suffer. Secondly, I think we are going to do more of these demonstrations. With

these new demonstration programs, we will know more of just what the answers ought to be. We will be making 25 demonstration grants to State health departments for a total of $1 million.

This will increase support for paraprofessionals, in identifying unmet needs of mothers, newborn children, and pregnant women.

We will have 25 nurse practitioner grants. This will require $2.4 million to provide services for school-age children.

We will have six school-based dental programs. We will have 14 testing programs for newborns, which will cost us $1.1 million. This will be used for screening for sickle cell, PKU, and six metabolic diseases.

And finally, we will have seven accident prevention programs in the States.

So, in fact, we will support a number of these demonstration projects; they will be large enough to give us the information and data that we need.

Senator MATHIAS. That is such a critical program and I hate to see it decreased. There are areas where I am sure we could make cuts. I have a great personal desire to see this program continue.

If you had more money, could you use it effectively and efficiently?

Dr. LYTHCOTT. Yes, sir. I believe that the amount needed to keep us up with inflation is $17.3 million. This would give us a 6-percent allowance for inflation.

Senator MATHIAS. What data do you have to indicate the effectiveness of the health program?

Dr. LYTHCOTT. Let me use some figures. The percentage of people trained who go to work in our projects includes: 80 percent of the physicians who work in maternal and child health programs; 50 percent of the dentists; 70 percent of the clinical psychologists; and 95 percent of the nurses.

Senator MATHIAS. So you think it is a highly effective training program?

Dr. LYTHCOTT. Yes.

MCH RESEARCH AND TRAINING

Senator MATHIAS. Now your biggest budget cut comes in the area of research and training. Fiscal 1979, it was $32 million. Fiscal 1980, you are requesting less than $15 million.

So here is a program which is reputed to be among your most effective, which is being cut the hardest.

What sort of impact is that going to have on the number of people trained?

Dr. LYTHCOTT. First of all, it was clearly a budgetary decision in a year of tight dollars. You have to make the cut somewhere.

As you know, we are a laying-on-hands administration. Our agency provides services and, from that point of view, if one has a zero-based budget, then he must put something down at the lower priority level.

It means we shall train only half of the people we trained last year. And, indeed, we will cut research by about 80 percent. But that is a purely budgetary judgment.

Senator MATHIAS. When I go out to prune a tree, I like to prune those outer branches, let them drop off on the ground. There is nothing—they aren't going to go any place.

I don't like to prune the trunk from which everything else is going to spring.

And it seems to me when you get out your research and your training, you're pruning the trunk.

I understand what you say. It was a budgetary decision. I am not going to ask you to comment on that fact. I suspect it wasn't a voluntary one as far as you were concerned.

But the committee has to deal with the whole picture here. And it seems to me that that is a very difficult decision.

How many research grant programs will probably be reduced as a result of this cut?

Dr. LYTHCOTT. Eighty percent of the research will be cut. We shall fund only 15 projects in fiscal year 1980. We shall not fund the other 40 which were supported last year.

Senator MATHIAS. Will they find new funding somewhere else?

Dr. LYTHCOTT. I suspect that a few of them will, sir.

Senator MATHIAS. Do you have any idea where?

Dr. LYTHCOTT. Well, in this area, they may well get it from the NIH or private foundations.

Senator MATHIAS. Well, let's say it comes from NIH. In that event, there's no net overall budget impact from the cut.

So wouldn't it be more orderly to keep the funding where it is?

Dr. LYTHCOTT. That is not a judgment I think I am prepared to make. As you know, both the bureau and the agency took this decision, faced with a certain number of dollars.

PHS HOSPITALS AND CLINICS

Senator MATHIAS. Well, did they comment on the fact that the child health budget was a level budget, so there isn't any high degree of likelihood that there is any relief from that source and the private foundations have tightened up their pursestrings——

Again, I'm not fussing with you personally, Doctor. I suspect we are on the same side of the table as far as our hearts are concerned. But I am worried about the program.

Well, let's pass on to the Public Health Service hospitals and clinics, a subject which is close to my heart.

We have a Public Health Service hospital in Baltimore. Can you state categorically that all Public Health Service hospitals and clinics under your budget request, both supplemental and in the 1980 budget request, will be in compliance with the provisions of Public Law 93-155?

Dr. LYTHCOTT. Yes, we shall be in compliance with Public Law 93-155. That is one thing we have been very careful about this year.

Senator MATHIAS. As you know, Chairman—Senator Magnuson has a great personal interest to support public health programs; and I would be remiss if we didn't make that a part of this record, because he has a real and personal interest in it.

Now, in the question, patient care positions, the Public Health Service hospitals appear to be understaffed. That was an overstatement?

Dr. LYTHCOTT. Let me put it this way. We are not below the 1973 level of staffing. Actually, we are a few above the budgeted position level of 1973.

Today we have 5,516 budgeted positions, an increase of 37 positions over 1973.

Senator MATHIAS. But the level of staffing really can't be related only to a given date; it has to be related to the patient load, the relative patient load at a given date.

Dr. LYTHCOTT. The Secretary chartered an ad hoc committee to look at the hospitals' present and future roles. He did that in January 1978 and the committee reported their findings to the Secretary in August 1978. The Secretary then directed a task force to implement a number of the committee recommendations.

One of the reasons we have not been willing to discuss an increase in the budget was because we are awaiting the implementation plans from that task force. And it may be a different set of recommendations than those made by previous administrations.

Senator MATHIAS. Would you be able to tell us whether or not, as a result of the current staffing level, the patient care is being reduced, some of the services rendered to patients have been cut back?

Dr. LYTHCOTT. The quality of the patient care has not been reduced. I would like to refer to Dr. Erickson on this point.

QUALITY AND QUANTITY OF PATIENT CARE

Senator MATHIAS. Just so we don't argue about semantics, let's not talk about just the quality of patient care, but the quantity of it as well.

Dr. ERICKSON. I'm not aware that the total quantity has been reduced. Our outpatient loads, for example, have continued to go up. Hopefully, we are doing a better job by the prevention you have spoken of.

I think it's important also to note that the man-years, as opposed to the positions, are significantly on the increase.

Now, look at the data from 1973, for example. We had only 4,614 person-years in 1973. That's continued to climb, so that the actual figure for 1978 was 5,541 person-years. And we estimate for 1979 that it will be approximately the same.

And, you know, the lapse rates tend to change. We had large lapse rates in 1973 because of the threat of closure and so forth. But now the person-years are significantly above the level that they were then. And I think the number of inpatients has stayed relatively the same.

Also, our outpatient population should stay relatively the same. The outpatient visits, for example, in 1973, were 1.5 million—then in 1974, they went down; in 1975, they were back about the same level. In 1980 they will be up to 1.8 million from 1.7 million in 1979.

The admissions have stayed relatively in the 30,000-plus range. They're a little up. In 1977, they were 33,509. The actual for 1978

was a slight decrease, to 32,925. We are projected back up to the 33,000 figure for this year. So the numbers have grown since 1973, and hopefully it is because we found ways to be more efficient with the man-hours we have.

Senator MATHIAS. But your testimony is that the patient care is not being cut back?

Dr. ERICKSON. Based on the figures that I have, I can't see where it's being cut back. The total output has gone up.

Maybe we have increased productivity.

PHS HOSPITALS AND CLINICS—1979 STAFFING

Senator MATHIAS. Well, you currently have 5,516 posts today. You project, by the end of fiscal year 1979, 5,265 positions; is that right?

Dr. ERICKSON. No, sir; our current budget provides for 5,516 positions.

Senator MATHIAS. In other words, you are talking about the level?

Dr. ERICKSON. We are talking about the number of budgeted positions in 1979, 5,516.

As you know, Senator Mathias, the positions requested by the President in 1978 and 1979 were the same. In 1978, the Congress added 125 positions above the President's request. For 1979, the Congress added 50 positions to the budget request, so we did take a 75 position reduction in fiscal year 1979.

Senator MATHIAS. Well, what is your ceiling?

Dr. LYTHCOTT. The current ceiling for hospitals and clinics is 5,516.

Senator MATHIAS. Year-end ceiling; that is what I'm trying to get to. Maybe I didn't ask my question clearly.

So we don't get lost in the jargon, let's talk about living, breathing human beings. How many people are onboard?

Dr. ERICKSON. We project for 1980 that we will have 5,295. That is person-years. That is living, breathing people.

Senator MATHIAS. Now, how many living, breathing human beings have you onboard today?

Dr. ERICKSON. 5,461, if through the end of this year, if our figures are correct; and last year the actual for 1978 was 5,541.

Senator MATHIAS. All right.

Now, what is the difference between those two figures?

Dr. ERICKSON. The difference between the two is the difference between 5,295 and 5,461.

1980 STAFFING OF PHS HOSPITALS AND CLINICS

Senator MATHIAS. So we will have a decrease of about 166?

Dr. ERICKSON. We are presently estimating a reduction of 166 man-years between 1979 and 1980. That's based on a projected lapse rate of about 4 percent during 1980, as opposed to the 1-percent lapse rate in 1979. We have run lapse rates anywhere from 15.8 percent back in 1973, down to lows of around 1 percent; it tends to fluctuate.

Senator MATHIAS. But suppose there is no lapse rate in the hospital?

Dr. ERICKSON. Well, if there is no lapse rate in the hospital and clinic system then you would essentially be staffed very close to your budgeted position ceiling all the time.

Senator MATHIAS. Would you let them do that?

Dr. ERICKSON. Yes, but in my experience, it is hardly ever possible to run no lapse rate, because by the time one person decides to move on to do something else, you can't until that person tells you he is going to leave, recruit for his replacement; and you normally lose some time in replacing people who do move on—nurses particularly, because of marriage or new geographic locations or for whatever reasons. And that is what maintains your lapse rate.

Senator MATHIAS. Well, are you telling us now that the Department has the current intention of reduction of 166 positions till the end of the present fiscal year?

Dr. ERICKSON. No, sir. That is not a reduction of positions; the positions will remain the same in both 1979 and 1980, 5,516 positions. Due to the various influences that change the motivations of people to find different employment and due to the lower number of positions budgeted in 1979 versus 1978, we currently estimate an increased lapse rate in 1980 compared to 1979. This higher lapse is projected to reduce our man-years in 1980 by 166.

PHS HOSPITALS AND CLINICS—HIRING

Senator MATHIAS. Well, in the light of my own uncertainty about exactly where we are, and in the light of Senator Magnuson's very great interest in this, I will make this suggestion: We ask you to supply for the record the number of people each hospital and each clinic hire, based on a rate of 5,516.

Then I think we have some definite and concrete base on which we can make our judgments.

Dr. LYTHCOTT. We will provide that for the record, sir.

[The information follows:]

PHS HOSPITAL AND CLINIC SYSTEM STAFFING

Facility	1979 budgeted positions	1980 estimated positions
Baltimore	536	536
Boston	297	297
Carville	312	312
Nassau Bay	312	312
New Orleans	674	674
Norfolk	336	336
San Francisco	682	682
Seattle	548	548
Staten Island	1,053	1,053
Subtotal, hospitals	4,750	4,750
Atlanta	13	13
Buffalo	10	10
Charleston	7	7
Chicago	40	40
Cincinnati	14	14
Cleveland	17	17
Detroit	33	33

PHS HOSPITAL AND CLINIC SYSTEM STAFFING—Continued

Facility	1979 budgeted positions	1980 estimated positions
Galveston	22	22
Honolulu	34	34
Houston	21	21
Jacksonville	16	16
Memphis	34	34
Miami	33	33
Mobile	22	22
New York	82	82
Philadelphia	27	27
Pittsburgh	7	7
Port Arthur	7	7
Portland, Maine	16	16
Portland, Oreg	14	14
St. Louis	25	25
San Diego	33	33
San Juan	27	27
San Pedro	59	59
Savannah	34	34
Tampa	35	35
Washington, D.C.	84	84
Subtotal, clinics	766	766
Total	5,516	5,516

Senator MATHIAS. And is it your testimony that the Department contemplate this reduction of 166, which we have just discussed, but no further reductions?

Mr. FORBUSH. I'm not sure there is a reduction there at all.

Dr. ERICKSON. The same number of positions budgeted in 1979 are being requested for 1980. Only the estimated number of man-years is projected to be lower in 1980.

Mr. FORBUSH. I am speaking of ceiling now, as opposed to man-years, which is another valid way to measure employment. We used the November 30 on duty numbers as our starting point. The ceiling we calculated for the Public Health Service assumed no reduction in patient care activities below on-duty personnel as of November 30.

So the end of 1979 ceiling should not require any reductions below that level.

Senator MATHIAS. You don't see any reductions in public health services?

Mr. FORBUSH. It would not require that. In translating that into actual program activities——

Senator MATHIAS. "Would not require" it, but what are the intentions of the Department?

Mr. FORBUSH. It was—yes, sir. We don't want to interpose a judgment. If PHS believes that particular objective could be achieved with somewhat less personnel, they would be free to do that.

Senator MATHIAS. The circumstances allowing, an earthquake could knock the hospital down. This committee wouldn't expect you to keep employees on full pay. [Laughter.]

44-812 O - 79 - 8

ABSORPTION OF OCTOBER 1978 PAY RAISE

You understand the concern I am expressing here is in the kind—to see that the quality health care is delivered.

Well, let's look at another aspect of Public Health Service hospitals. What method has been adopted to absorb the mandated pay increase under the fiscal year 1979? Are you going to absorb it out of the budget? It is an item of about, I believe, $12 million. And if that has to come out of the remaining quarters of fiscal 1979, the committee has some concern that it will reduce the amount available for patient care and equipment to the program.

Dr. LYTHCOTT. It is actually $12,900,000.

Senator MATHIAS. Worse than I thought.

Dr. LYTHCOTT. Of the $12.9 million appropriated for the PHS hospitals and clinics being utilized to cover the October 1978 pay raise, $6.1 million will be obligated within the Bureau of Medical Services. The remaining $6.8 million will be utilized by other programs administered by the Health Services Administration.

Senator MATHIAS. And what will be the impact on that program?

Dr. LYTHCOTT. I will be happy to provide the impact of this decision for the record.

Senator MATHIAS. If you would, provide it for the record.

[The information follows:]

PHS HOSPITAL AND CLINIC SYSTEM

Impact of the reduction to fund the fiscal year 1979 pay raise:	*In millions*
Curtailment of the second year of the 3-year equipment replacement and technology advancement program	$5.0
Imposition of a 1-percent lapse rate on full-time permanent personnel	1.2
Reduction of planned development of primary care, community outreach and ambulatory care programs	2.0
Reduction of funds required to perform maintenance and repair of PHS hospitals and clinics	4.7
Total	12.9

Dr. LYTHCOTT. There have been reductions to accommodate this. In other words, nondirect patient care activities.

Senator MATHIAS. But, again, I go back to my pruning analysis. Here, if you are cutting off the trunk, you have got to expect less fruit somewhere down the line to pay for it sooner or later. And that is a pretty good chunk; isn't it?

Dr. LYTHCOTT. It is, sir. It is a sizable chunk. But that was the judgment that the Department made.

Senator MATHIAS. Again, it is a budgetary judgment.

Mr. FORBUSH. We tried to absorb as much of the total cost of $173 million as possible. We are proposing to absorb $75 million, including some——

Senator MATHIAS. Was there an agency request for supplementals?

Mr. FORBUSH. I am not sure. I imagine there was.

Dr. LYTHCOTT. There was not, sir.

Senator MATHIAS. You didn't request it?

Dr. LYTHCOTT. Yes, sir. We did request it. If you will forgive me.

Senator MATHIAS. Then you felt at the time you made the request it would be harmful to take this much out of the hide of the program?

Dr. LYTHCOTT. Not necessarily, sir. Perhaps what I was trying to do was to make out well with the available money.

Senator MATHIAS. Well, I think that was well said, Doctor.

What I am afraid of—and I am saving all the money we can, and I understand the pressure is on the Secretary, and I understand the pressure is on you and everybody in similar positions, and we have to have those pressures if we are going to achieve the kind of lower rate of inflation which all of us really feel is absolutely essential. But I don't think it pays to use the cosmetic approaches to these problems and to make it look better on this balance sheet but have it end up somewhere on this one.

We are not really getting ahead of the problem, and I think the committee is going to have to look at this particular item very hard.

Dr. LYTHCOTT. Yes, sir.

INSTRUCTIONS TO TECHNICAL QUESTIONS

Senator MATHIAS. Well, Doctor, we have some technical questions which I won't put to you orally this morning but which we will submit to you in writing. We would appreciate it if you would respond to them, in addition to the other information that we have requested during this hearing this morning. We would request that all questions and the hearing transcript, which you will receive, will be returned to the committee no later than 7 working days from today. And that will include, of course, the answers to the questions.

[The following questions were not asked at the hearing, but were submitted to the Department for response subsequent to the hearing:]

BREAKDOWN OF SUPPLEMENTAL REQUEST

Question: You are requesting a supplemental appropriation of $81.5 million for Community Health Centers program. Please explain what makes up the $81.5 million request.

Answer: The $81.5 million supplemental request will support 95 new rural community health centers providing access to health care for 190,000 people, and 4 new rural hospital affiliated primary care centers providing access to health care for 37,400 rural residents. In addition, $49.4 million of the supplemental request will be used to support 43 new inner-city health projects, which will provide health care access for 426,100 inner-city people. Finally, $15 million of the request will be utilized to support the expansion of capacity to provide services to 147,000 adolescents in rural and urban community health centers.

Question: What percent of this is for urban projects?

Answer: Approximately 67 percent or $54.4 million of our supplemental request will be for urban areas. This amount will be used to establish 43 new projects and provide access to health care for 475,100 urban people.

FISCAL YEAR 1979 AND 1980 SUPPORT

Question: How many new projects will be funded in fiscal years 1979 and 1980 for both the rural underserved program and the urban underserved program?

Answer: In 1979, 142 new projects will be funded. Of this total 99 new projects will be located in rural areas while 43 new centers will be established in urban areas.

For 1980 our budget request proposes the establishment of 45 new projects. Of this number, 34 projects will be for rural areas while the remaining 11 centers will be located in urban areas.

GAO REPORT

Question: The GAO Report which we mentioned earlier spoke of 112 "neighborhood health centers" that are funded by HEW and that are intended to provide outpatient health services to residents of areas designated as medically underserved areas. It went on to say that many centers are not operating very efficiently because they are not properly staffed. Some serve residents of areas that are not designated as medically underserved, while most medically underserved areas go without health center services. The report states that reducing overstaffing and inefficient centers could provide savings to reach more of the medically underserved. How much money, in fact, could be saved and used in other areas by reducing overstaffing?

Answer: A major policy implication drawn by the GAO study was that the cost implications and poor management of community health centers required that money be reprogrammed into new areas, that certain centers should be closed, and that a vast out-year commitment would be necessary if this model were expanded. Between fiscal year 1974 and fiscal year 1976, over $25 million was moved from continuation support to initiate new projects serving additional areas. Yet during that time, those same 112 projects reflected a 30 percent increase in users, a significant management and productivity achievement.

Question: How do you intend to accomplish this?

Answer: We are continuing our efforts to implement new and revised program indicators and funding criteria in improving project efficiency and effectiveness. Revised program indicators such as project utilization, physician productivity, administrative costs, and clinical effectiveness are being used to assure closer evaluation of the effectiveness and efficiency of the project management. Funding decisions for centers are based on reported project users and encounters and objective assessment of each project's performance in accord with these program indicators. The Bureau Common Reporting Requirement system became completely operational during the last quarter of fiscal year 1976. The reports generated by this system are provided to our Regional Offices for use in ensuring that projects are in compliance with requirements. Activities designed to improve overall compliance are continuing as evidenced by the use of new and more stringent indicators and by the redirection of funds previously expended for excessive administrative costs to the provision of medical services.

In May 1978, revised funding criteria for our programs were issued. These criteria include revised program indicators which set a norm/standard of between 4,200 and 6,000 onsite encounters per staff personnel equivalent physicians per year. These program indicators have been identified as one funding criterion which will be formally used by the Regional Offices in determining appropriate levels of grant support.

ENFORCEMENT OF STANDARDS

Question: GAO previously reported on the underuse of health center physicians, and apparently HEW did develop productivity standards and staffing ratios for evaluating health center utilization. Why have these standards now in existence not been adequately enforced?

Answer: We have taken vigorous steps to enforce program indicators and to assist projects in improving their performance. For example, in computing regional allocations for continuation awards for Community Health Centers, the amount used by projects for administrative overhead in excess of the standard, which is 20 percent, is subtracted from their allocation. In addition, we have provided technical assistance to projects to help them comply with our program indicators.

Further steps to strengthen present productivity have been and will continue to be undertaken through judicious application and enforcement of newly revised program indicators. However, we considered it critical to point out that these indicator norms are dynamic. The physician productivity indicator during the GAO study period was for 2.7 encounters per hour which calculates to 3,947 per year against the aggregated average annual hours of clinical activity for full time equivalent physician. Our current norm has been raised to 4,200 encounters per year, reflecting an even higher productivity standard.

An example of how the productivity standards have in fact been enforced is the reduction in administrative overhead at our health centers. Since we initiated the standard on administrative costs, we have seen a 3 percent decrease in these funds; this amounts to over $7.1 million, in savings expended for this purpose.

Question: How do you justify asking for continual increases for these centers if they aren't doing their job properly?

Answer: We feel that our centers are doing their jobs properly. Through data submitted by projects via the Bureau Common Reporting Requirements, we continuously review data related to providers, patients and costs. If a determination is made that a grantee is not providing efficient high quality service, an effort is made to work with the grantee to improve the project's performance. If the existing grantee cannot be brought into compliance, the project award may be made to another entity so that continued service may be provided to the community.

In 1980, the 965 community health centers will have the capacity to serve 5.6 million rural and urban medically underserved residents, an increase of 38 percent over 1978. During this time, while experiencing increased productivity we also have been able to significantly decrease administrative overhead.

RURAL AND URBAN MEDICALLY UNDERSERVED AREAS

Question: Forty-nine million people reside in approximately 7,400 urban and rural medically underserved areas. How many people reside in rural underserved areas versus urban underserved areas?

Answer: Of the 49 million people residing in medically underserved areas, 22 million are located in urban areas while 27 million reside in rural underserved areas.

Question: What proportion of funding is allowed for urban areas and rural areas?

Answer: Sixty percent or approximately $235 million of our 1980 request is for urban areas, while 40 percent or $154 million will be for rural areas.

Question: In how many medically underserved areas have rural health initiative projects been established?

Answer: In 1978, there were 1,930 medically underserved areas in the non-Standard Metropolitan Statistical Areas of the United States. In 1978, 809 or 41.9 percent of these areas were served by a primary care project.

Question: What portion of the underserved population living in rural areas is served by rural health initiative projects?

Answer: Our 1980 budget will provide access to health care to appoximately 2.9 million rural residents. This represents 11 percent of the total rural need.

Question: What is the grant cost per person served in rural health initiative projects versus those in inner-city programs?

Answer: The grant cost per person served is $100 to $120 in rural projects, and $150 per person served in urban projects.

RURAL HEALTH PROGRAMS

Question: Senator Robert Byrd would like you to answer the following questions. He, too, is concerned about emphasis being placed on Rural programs. Doesn't the new Section 330 of the Public Health Service Act require that the total number of people served under that program reflect the rural/urban split in the medically underserved population (60 percent rural-40 percent urban) and since at present the number of urban people served exceeds those in rural areas, and since each rural clinic serves a smaller number of patients, how many of the 142 new starts in FY 1979 and 45 new starts in FY 1980 will be rural clinics?

Answer: Section 330 of the Public Health Service Act requires that the Community health centers program maintain, within its funding level, a proportionately equitable relationship between the number of persons capable of being served in projects in rural and in urban medically underserved areas. This proportion will be no less than 40 percent urban or rural and no greater than 60 percent urban or rural for the additional population to be served. In 1980, 55 percent or 60,000 of the increased service capacity in Section 330 projects will be for rural areas, while 45 percent or 50,000 will be for urban locations.

In 1979, there will be 142 new starts. Ninety-nine of these new projects will be located in rural areas while 43 new centers, under the inner-city health initiative, will be established in urban areas.

For 1980, our budget is proposing the establishment of 45 new centers. Thirty-four of these new projects will be in rural areas, while the remaining 11 centers will be established in urban locations.

Question: What will be the dollar value of the rural clinic grants compared to the urban in each of those years?

Answer: For 1979, the estimated budget for the community health centers program is $359 million. Sixty-two percent or $223 million will be for urban areas, while the remaining 38 percent or $136 million will be for rural areas.

In 1980, our request is for $389 million. Of this amount, 60 percent or $235 million will be for urban areas, and 40 percent or $154 million will be for rural areas.

Question: What is the number of rural versus urban people to be served with the new start funds in FY 1979 and FY 1980?

Answer: In 1979 funds to support the 142 new starts will provide access to health care for 800,500 additional people. In rural areas, capacity for an additional 325,400 people will be established through 99 new rural centers. During this same time 475,100 additional urban residents will be provided access to health care in 43 newly established inner-city health projects.

For 1980, the funds supporting the 45 new starts will provide access to health care to an additional 203,400 people. Of this total 97,400 people will be provided access to health care in 34 new rural projects while the 11 new urban projects will provide capacity to health services to 106,000 urban residents.

RURAL CLINICS PROJECTIONS

Question: At the end of FY 1978, 79 and 80, what will be the total number of rural clinics in operation, the number of patients served, and the total population served?

Answer: At the end of 1978 there were 505 rural centers in operation. It is estimated that by the end of 1979 there will be 682 rural projects, and by 1980 a total of 716 rural projects will be in operation.

In 1978, the 505 rural centers actually served 1.5 million people, while providing access to health services for over 2 million rural residents. For 1979, the 682 rural projects will serve 2 million people, while providing capacity to health care for 2.8 million rural people. Our 1980 budget request of 716 rural projects will serve 2.4 million rural residents while providing access to health care to approximately 2.9 million rural people.

Question: Can you give me the same figures for all three years for urban clinics?

Answer: For urban areas, at the end of 1978 there were 190 projects in operation. It is estimated that in 1979, 238 urban centers will be in operation, and that by the end of 1980 a total of 249 urban centers will be in operation.

For 1978, the 190 urban projects served 1.9 million people, while providing access to care for 2.1 million urban residents.

In 1979, the 238 urban centers will serve 2.1 million people and establish capacity for over 2.6 million people residing in urban areas. For 1980, a total of 2.5 million users will be served through the 249 urban centers. At the same time these centers will provide access to health care for a total of 2.8 million urban people.

EQUITABLE TREATMENT OF RURAL AND URBAN AREAS

Question: The health services legislation passed last year requires an equitable distribution between rural and urban areas of the new health center projects to be funded. Are you in compliance with this requirement in the Fiscal 1980 budget?

Answer: Yes, Mr. Chairman, we are in compliance with that requirement in our 1980 budget. In total the community health center program will provide for an increased service capacity for 203,500 rural and urban medically underserved residents. Of this increase 110,000 will be served in new centers funded under Section 330; 60,000 or 55 percent of the additional population will be provided service in rural areas and 50,000 or 45 percent will be served in urban areas. The remaining 93,500 will be served in new centers funded under Section 328; 37,400 in rural projects and 56,100 in urban centers.

PRODUCTIVITY OF LARGE VS. SMALL CLINICS

Question: Are you expecting the same levels of productivity from small clinics as you are of the large ones (those with four or more medical providers)?

Answer: The level of productivity is related to the numbers of providers on the staff of the clinic. Each full time on site physician is expected to see between 4,200 and 6,000 patients per year and each midlevel practitioner is expected to see between 2,100 and 3,000 patients per year.

Question: If so, does this overlook and penalize the small clinics for efficiently using medical providers in a number of non-medical roles?

Answer: Small clinics are not penalized solely for their inability to reach productivity levels expected of providers. Where medical staff spend less than full time as providers, the numbers of encounters expected is adjusted in proportion to the time spent as a provider. The Bureau of Community Health Services uses several program indicators to monitor its primary health care programs to determine the appropriate level of grant support including the percent of total ambulatory care costs attributing to administration, housekeeping, and maintenance. A maximum of 20 percent is allowed. Also, encounters per full time provider staff, and charges as a percentage of reimbursable costs, to be no less than 90 percent, are taken into consideration. Projects are expected to be in full compliance with the program indicators by the end of their second full year

of delivering services, but projects may request exceptions from these criteria if the project operates in a way that a particular criterion is not appropriate. Each continuation application is judged on its merits and exceptions to meeting the program indicators can be made when circumstances warrant.

Question: How many of the projects funded under Section 330 are located in places with populations of 2500 or less?

Answer: Grantees do not provide information on the population of the place in which they are located, but do furnish information on the populations of the proposed service area. While many of the projects may be located in places where there is a population of 2,500 people or less, only two of the projects funded under Section 330 are known to have service area populations of 2,500 or less. The density of population in the service area is another importantant element when looking at the location of projects. For example, the density of population within a service area of a small rural clinic may be less than one person per square mile in an area which might cover 1,000 or more square miles, while the density of population for an urban project may be 10,000 persons or more per square mile.

Question: How many of the HURA projects are located in places with populations of 2500 or less?

Answer: As in the case of projects funded under Section 330, grantees do not provide information on the population of the place in which they are located, but do furnish information on the population within the proposed service area. Four HURA projects have service area populations of 2,500 people or less.

REQUIREMENT FOR GOVERNING BOARD

Question: Why is it that Region IV -- Atlanta -- is requiring Mary Holmes College in Mississippi to set up an umbrella system for several individual clinics but Region III -- Philadelphia -- won't give a Section 330 grant to 8 clinics now operated by the Southern West Virginia Regional Health Council which has a regionally represented board?

Answer: Mary Homes College in West Point, Mississippi, was funded by the Department of Health, Education, and Welfare, Region IV, with a $25,000 planning and development grant to create primary care organizations in the eastern part of Mississippi. They have assisted two communities to date and will not have any administrative responsibilities for the projects. The DHEW Region III office has not received an application from the Southern West Virginia Regional Health Council to create an umbrella administrative organization. They are encouraging such organizations.

Question: What is the geographic distribution of projects proposed for funding under Sections 330 and 329?

Answer: Of the 916 projects proposed for funding under Sections 330 and 329, 49 are in Region I, 81 in Region II, 112 in Region III, 269 in Region IV, 111 in Region V, 89 in Region VI, 32 in Region VII, 57 in Region VIII, 70 in Region IX, and 46 in Region X.

COMMUNITY HEALTH CENTERS - PREGNANCY PREVENTION INITIATIVE

Question: Your budget justification states that part of the funds for community health centers will provide comprehensive health care services to adolescents, especially with regard to pregnancy, venereal disease, drugs, alcohol abuse and emotional disorders. How does your pregnancy program relate to the adolescent pregnancy program which is requested at a level of $60 million in fiscl year 1980 in the Office of the Assistant Secretary for Health?

Answer: In fiscal year 1978, the Community Health Centers program expended $14 million for supplemental grants to develop adolescent health programs within family oriented, comprehensive health care delivery projects. This activity was in direct response to the Secretary's intention to develop and promote programs which were "Alternatives to Abortions." As a result of that activity, we funded 148 projects which would enable 136,000 additional adolescents to receive comprehensive health care service through these projects.

Included within the fiscal year 1979 supplemental budget request is $15 million in new grant funds to expand this activity. Our fiscal year 1979 work plans project an additional 150 of these grants to be awarded in fiscal year 1979, which will serve 147,000 additional adolescents.

The objectives of our adolescent health program carried on by the community health centers is designed to extend the availability, accessibility, and acceptability of family planning services to teenagers as a means of decreasing teenage pregnancies. We also develop comprehensive, coordinated services for pregnant teenagers and their babies in order to improve outcome for both the mother and baby. Such services would include medical, psychological, social, educational, vocational and other supportive services necessary during and following pregnancy.

The adolescent health services and pregnancy prevention program operating within the Office of the Assistant Secretary for Health will provide grants to help States and communities develop comprehensive community programs for adolescents which will develop linkages with community institutions, such as schools, churches, social service agencies, family planning clinics, and other health providers that can provide supportive services for adolescents. It is our intention that these centers, through meeting a variety of needs of teenagers for

social, recreational, legal, financial and medical assistance, will be increasingly effective in reaching larger numbers of teenagers.

BLACK LUNG SERVICES

Question: In fiscal 1979, Congress allowed $7.5 million for black lung services. You are requesting the same amount for fiscal year 1980. Will you briefly describe for the Committee how these funds have been utilized and what your plans are for the future for this program?

Answer: By the end of fiscal year 1979, we expect to provide support to 75 black lung service sites. Support for this program will be provided directly to local providers, to State agencies to establish statewide programs which contract with local providers, and to ongoing United Mineworkers of American health clinics.

These programs will probably enroll only about 2,000 to 3,000 patients by the end of the year, but should be capable of enrolling ten times that amount as they become fully operational. Future funding will permit projects to expand their services. Black lung service sites will provide case finding, medical evaluation and treatment; patient and family education; and follow-up outreach services.

Question: What is the total need in terms of black lung programs?

Answer: It is estimated that there are over 400,000 people who need access to clinical services.

LONG-RANGE GOALS

Question: Would you please share with this Committee your long-range goals in this area as well as what, in terms of national policy, Congress should be doing, in your opinion?

Answer: Long range goals will be to establish access to health services that will meet the particular needs of the people in a service area, including those suffering with black lung disease. The treatment regime we are supporting has been proven effective for people with chronic obstuctive lung disease, including black lung. The same concept of treatment which emphasizes good patient education and provisions to assure careful follow-up and continuity of care, should also be available to other chronically ill persons. Based on our experience with black lung, the Congress should continue to require, then, that community health centers supported with Federal project grants provide such comprehensive services and that Federal reimbursement programs (i.e., Medicare and Medicaid) be required, as a cost containment measure, to pay for such services. We expect to develop data to support many empirical observations that these measures (patient education and careful follow-up) will substantially reduce the need for costly acute care, especially inpatient care.

BLACK LUNG CLINICS

Question: What is the status of the Black Lung Clinics program for which Congress provided $7.5 million last year?

Answer: The notice of funds availability and invitation to submit applications will be published in the Federal Register by April 1. Review by the health systems agencies and A-95 entities and the normal time required for review and processing of applications will dictate that most awards will be made in the last quarter of fiscal year 1979. A broad spectrum of interested groups such as the United Mine Workers, the National Black Lung Association, and the Appalachian Regional Commission have assisted us by commenting on proposed program guidance which we now expect to issue in March.

Question: Have you issued regulations yet?

Answer: Yes, regulations were issued at the time of the previous appropriation in 1974. We will begin to implement the program under these regulations as they stand. We are proposing some amendments, however, which will allow greater responsiveness in the way the program is administered.

Question: Have you decided whether to set up any new clinics -- or will you just use existing ones?

Answer: We do not anticipate setting up any free-standing black lung clinics. Most of the support will go to existing community based providers, to allow them to expand their diagnostic and treatment services to meet the special needs of people with black lung and to provide outreach to find and enroll these people. Because of the importance of good primary medical care, we expect most of the clinics to be established in primary health care centers, but in some instances a community hospital or even a local public health department may be able to assure access to all services through agreements with other providers. We will also continue to support the United Mine Workers in their assistance to the clinics they have developed.

CUT IN HURA PROJECTS

Question: Your request for Health in Underserved Rural Areas (HURA) projects is $9 million in fiscal 1980. This appears to be a cut of $7.4 million from the FY 79 appropriation. Is it actually a reduction?

Answer: Mr. Chairman, the Health Underserved Rural Areas program was not decreased by $7.4 million in 1980 from the 1979 appropriation. In 1979, there were 112 HURA service projects providing access to health care to 493,000 people. These projects were funded at a cost of $16.5 million. In 1980, these same 112 projects, providing health care capacity to the same 493,000 people will be supported under both the HURA and Community Health Centers authorities at a total funding level of

$15 million. In accordance with P.L. 95-626, Section 340 will continue to support 66 HURA research and demonstration projects at a total cost of $9.1 million, while 46 HURA service projects are being transferred to the community health centers program, Section 330, at a cost of $5.9 million.

In 1980, there will be a $1.5 million decrease for the HURA projects. This is a result of the fact that the $1.5 million increase appropriated by the Congress in 1979 was used to build up capacity in the 66 HURA research and demonstration projects. In 1980, having built up the capacity in these projects which will allow for the increased collection of patient fees as well as third party reimbursements, the additional $1.5 million will no longer be needed. I should mention that these projects will continue to maintain the same level of services provided in 1979 despite the reduction in grant funding.

Question: If the balance of the HURA projects were transferred to another authority -- Sec. 330 of the PHS Act --, will they retain their HURA character or be transformed into another type of rural health center?

Answer: The 46 projects which will be transferred from Section 340 authority to Section 330 funding will provide the full scope of primary health care services as required by Section 330 of the Public Health Service Act.

HOME HEALTH REDUCTION

Question: In fiscal 1978 and 1979, $6 million was provided for home health services. Your budget request for fiscal 1980 is only $804,000. Could you explain to the Committee what rationale you are using and why you are suggesting that the home health services be phased out so rapidly and completely?

Answer: The $804,000 contained in our budget request for the home health program provides support to fund 14 expansion projects, and represents sufficient funding for an orderly phaseout of this program. We believe that the Home Health program has successfully demonstrated that, based upon the comparative cost of $26 per home health visit and $243 per day for inpatient hospital services, there are reasonable indications that home health services are cost effective. As a result, we believe that State and local governments, through the use of public funds and funds available from private sources, could now finance the development of new and expansion of existing home health agencies. In addition, third party funding is available under the Social Security Act to finance the continued operation of home health agencies.

Question: HEW has funded many studies relating to the general topic of alternatives to institutional care. Many of these studies focus on home health care and attempt to assess, among other factors, the cost effectiveness of home health care. What conclusions have these studies arrived at and in what way will these findings be integrated into policy?

Answer: This Agency's Office of Planning, Evaluation and Legislation, contracted in 1977 for studies to be carried out on the cost effectiveness of home health services. The results of that research found that home health services did provide cost savings through earlier patient discharges from hospitals. A General Accounting Office study, published in December 1977 and entitled "Home Health - The Need for a National Policy to Better Provide for the Elderly", concluded that home health care in the treatment of the elderly was a cost effective alternative to nursing home care in all but 17% of the total elderly noninstitutionalized population.

The cost effectiveness of home health care is traditionally measured in tems of the difference between the cost of home health services and the cost of alternative modes of patient care. However, studies have failed to conclude that increasing the availability and utilization of home health services would be accompanied by a national reduction in the expenditures for both hospital and long term institutional care. Economic forces within our health care delivery system tend to fill acute and long term care beds as soon as they are vacated. Therefore, the increased utilization of home health services may not significantly reduce the nation's cost of inpatient care. Therefore, HEW's policies have concentrated on reducing the number of unneeded acute and long term care facility beds and concurrently expanding the availability and accessibility of home health services.

Question: How many of the existing home health care grants that operated in fiscal 1978 and 1979 will be able to continue presently operated projects?

Answer: All projects funded in 1978 and 1979 will be able to continue without the additional support of Home Health Services project grant funds. Grants are awarded for a 12-17 month period. Before funding is provided, assurance must be provided that the applicant can become financially viable at the end of the grant period. All projects funded in fiscal years 1976 through 1978 were successful in receiving Medicare certification and remaining financially viable at the end of the period of Federal project support.

Question: How many people would be served in this manner?

Answer: It is estimated that for each $1 million of grant funds appropriated under the Home Health Services grant program an additional 5,000 persons will be served as a result of increased home health services capacity development.

Question: If possible, would you please give us estimates of the savings which could result in the United States due to home health-type care?

Answer: Data are not available from which to make national projections on savings attributable to the utilization of home health services. For example, home health utilization by the

medicare population ranges from a high of 202 home health visits provided to each 100 medicare eligibles in the highest utilization State to 14 visits per 100 medicare eligibles in the lowest utilization State. The mean for all States is 69 visits per 100 medicare eligibles using 1977 data. Existing data do not show a correlation between the increased utilization of home health services and a decrease in the number of acute and long term care facility bed days used per medicare beneficiary. While it is hypothesized that home health services does reduce the need for institutional care, the present level of data availability does not allow this hypothesis to be documented.

FLEXIBILITY OF FUNDING UNDER COMPREHENSIVE GRANTS

Question: The Comprehensive Grants program in the past has given a great deal of flexibility to the States in terms of how they utilize the funding they receive under this authority. Is it a fair statement to say that that flexibility has also made it extremely hard to identify the specific accomplishments of the States under this authority or to evaluate the impact on health status nationwide?

Answer: Yes, this formula grant program is primarily used as an incentive grant program to provide a base of support for comprehensive health services. As intended by law, the manner and purpose for which the funds were expended varies greatly according to States' needs. However, we never have been able to get adequate data from the States on the accomplishments of this program.

Question: Can you point to specific examples of where in fact this 314(d) or Comprehensive Health Grants funding has made a specific difference?

Answer: These grants provide funds to States for chronic disease programs, including heart disease, cancer, diabetes, and stroke; and health service delivery programs, including maternal and child health, home health, and dental activities. The largest percentage of 314(d) funds support personal health services which, when added to State resources, provide services to 53 million persons. Because it is a formula program, it is difficult to measure specific performance due to the fact that each State has latitude in deciding which health programs will be supported.

Question: Under what authority or where will the States find the funds to continue to operate the programs presently underway if the Congress were to agree to this budget reduction?

Answer: Several activities previously funded with 314(d) funds, such as preventive health services and mental health activities, will be supported through increased funding of these activities in programs in the Alcohol, Drug Abuse, and Mental Health Administration and the Center for Disease Control. Other authorities such as Title V of the Social Security Act, Maternal and Child Health; Section 330 of the Public Health Service Act, Community Health Centers, and the Hypertension program have

increased funding for 1980, and will assist States in addressing many of the same public health needs previously funded by the 314(d) program.

EVALUATION OF THE MATERNAL AND CHILD HEALTH PROGRAM

Question: How much is currently being spent on evaluations of the Maternal and Child Health program?

Answer: In 1978, $1.4 million was spent on evaluations concerning the Maternal and Child Health program. In 1979, an estimated $1.9 million will be spent on Maternal and Child Health evaluations.

Question: Last year, you advised us that the results of studies initiated at the close of fiscal year 77 would not be available until November or December of 78. Are these results now available, and if so, what do they show?

Answer: One study was for the purpose of evaluating the States' activities associated with the Improved Pregnancy Outcome program.

The evaluation's comparison of IPO and non-IPO areas showed that the areas with IPO programs have, in general, fared better than the comparison areas in terms of activity measures, worse in terms of final outcome measures, and about the same in terms of intermediate outcome measures. From the specific IPO/non-IPO comparisons, it was apparent that, of the States studied, the West Virginia IPO program has performed best to date relative to its comparison area, faring better in terms of activity measures and both sets of outcome measures. In addition, both the South Dakota program and the North Carolina program fared well in terms of their activity and intermediate outcome measures. These IPO programs filled numerous gaps in the perinatal care systems surrounding their operation. Relative to areas without IPO resources, the IPO areas took more advanced steps toward development of a regionalized system of care and generally placed a greater emphasis on identification/care of high-risk patients, tracking of patients, and efforts to assess quality of care and monitor pregnancy outcomes.

Another study dealt with development of a Child Health Strategy impact evaluation methodology. A theoretical methodology for evaluating certain aspects of the child health strategy based on vital statistics data was attempted focusing on three outcome measures -- birth cohort characteristics, survival probabilities, and infant mortality rates. Three methodological problems were encountered -- the estimation of program penetration rates; the level of data aggregation, and the role of exogenous factors in an accurate evaluation. To address these problems and assess the applicability of the methodology to real world conditions, four site visits were undertaken to Maternity and Infant Care projects. It was concluded by the study team that evaluation of Child Health Strategy components can be undertaken at some sites using vital statistics data.

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A third study was concerned with evaluation of hemophilia diagnosis and treatment centers. It was suggested by the contractor that the most appropriate policy is to permit a diversity in the area of care for hemophiliacs, allowing individual centers to pursue their own treatment modalities. The limited Federal program was determined to be highly cost effective and has resulted in the ability to serve more unserved hemophiliacs.

Question: Do you believe that the findings merit the costs of the evaluation efforts?

Answer: Yes, the examples above illustrate that the program does get data and analyses which can be useful in program, budget and legislative decisions.

MATERNAL AND CHILD HEALTH PROGRAM

Question: The Maternal and Child Health program is intended to extend and improve services to reduce infant and maternal mortality and morbidity. To accomplish this intent, HEW is authorized to provide formula grants to State health departments. With these funds the States are to provide needed services and to manage statewide maternal and child health efforts. During the past year HEW established several special initiatives, such as -- Improved Pregnancy Outcome and Improved Child Health -- which also are directed at improving either maternal or child health care. Is the need for the special initiative indicative of failure of the Maternal and Child Health program to accomplish its goals? If so, is the failure because of poor MCH management or lack of funds?

Answer: Not at all. The special initiatives of the Maternal and Child Health program are administered by the State Maternal and Child Health programs and are, therefore, a furtherance of the programs' goal to plan, promote, and coordinate the provision of health services to mothers and children. The additional emphasis placed on the Maternal and Child Health program through these initiatives should enable us to more effectively achieve the program goals.

Question: How much of the Maternal and Child Health program funds are actually spent on service delivery and how much are expended for the indirect management of the service delivery component?

Answer: Indirect cost rates for the administration of the Title V program range from 20 percent to 30 percent of the allocation. Some States do not deduct any amount from the grants. There is no breakdown of the amounts used to support State Maternal and Child Health and Crippled Children consultant staff as compared to the amount utilized for patient health care services. A special survey of the individual States would be necessary to determine the service delivery component.

Question: What portion of the HEW funding for the special initiatives is spent for management of the initiatives versus service delivery?

Answer: For special initiatives, administrative costs are limited to a 20 percent maximum of the allocation. In many instances, however, the administrative costs are less than the 20 percent allowed.

Question: Congress has legislated restrictions on the use of Medicaid funds for abortion purposes. How has this affected the direction of the Maternal and Child Health Program?

Answer: Title V funds are not used for abortions except under the strict observance of the Abortion Regulations which were issued on July 21, 1978. The legislative restrictions have not affected the direction of the MCH Program.

CHILD HEALTH GRANTS

Question: The remainder of your $12 million increase will be $1.4 million for dental health; $1.8 million for accident prevention; $1.1 million for newborn screening; approximately $4.2 million in immunization tracking programs; and $1 million in a program called "Expansion of Access to Services in State Health Departments." All of these programs appear to be so small in nature and funding that I really question the impact they could have on a national basis. Please comment on this and how you envision these programs in the future as to funding, and numbers of people they will be serving?

Answer: These project grants are designed to demonstrate effective programs to fill gaps in the system where the ongoing Maternal and Child Health programs are not providing adequate care. The new project grants will deal with screening and comprehensive medical and dental services for school age children, screening for metabolic disorders, accident prevention and additional problems of pregnancy related services. These new discretionary grant activities will enable the MCH program to target funding to meet specific needs, and will assure that funds will be specifically targeted to high infant mortality areas, areas with high accident rates and areas where dental care services are badly needed. Through the dental treatment program and the school-nurse practitioner activity alone, some 587,000 children will be served.

We feel that the $11.9 million increase presently requested is sufficient to demonstrate the need and success for these activities. Dependent upon the results provided by these demonstration grants, a decision will have to be made as to their continuation.

Question: Is it possible that this is just more fragmentation of Federal programs?

Answer: Not at all. All of these new discretionary grant activities will be carried out under Title V of the Social Security Act and will be either carried out or coordinated by State health departments. This will reduce fragmentation and assist the state health agencies in carrying out their statutory responsibility of extending and improving health services for mothers and children.

SCHOOL HEALTH

Question: Of your $12 million increase request, you ask that $2.4 million to support 25 grants to state health agencies go to develop school health programs. We already have school health education programs in the Office of the Assistant Secretary of Health, in the Center for Disease Control, and in the Office of Education. Specifically, how do you intend to coordinate all of these efforts to avoid overlap and waste? How will the work done under the 25 grants differ from what HEW already is doing under other programs?

Answer: The health education programs funded by the Department do not provide health care services. The request for funds to support grants to State health agencies is for the provision of health services to school age children. Services will be provided by State and/or local health departments. The coordination of health education programs supported by other agencies will be accomplished through the State health agency; more specifically through the State Maternal and Child Health unit within the State agency. These grants will not duplicate or overlap the programs administered by the Center for Disease Control or the Office of Education but rather will complement them.

EPDST

Question: In the last several years, Medicaid's Early Periodic Detection Screening and Treatment -- EPSDT -- program has grown and is now screening and treating a significant number of children. What have you done to coordinate the efforts of the Maternal and Child Health program with the EPSDT program?

Answer: This Agency and the Health Care Financing Administration have issued joint policies and guidelines and have jointly conducted workshops for State Maternal and Child Health, Crippled Children's and State Medicaid/EPSDT staff concerning the coordination of efforts at the State and local levels for provision of services to EPSDT eligible children. Efforts coordinating these programs continue at the Federal level.

Question: Do you believe that EPSDT and Maternal and Child Health are duplicating one another? If not, how do they differ?

Answer: EPSDT and Maternal and Child Health programs are not duplicative of one another. The EPSDT program is a part of the Medicaid program and is essentially a means of financing services to EPSDT eligible children. The Maternal and Child Health program promotes, plans, coordinates, and provides

services and, by Federal statute, is to be utilized and reimbursed for the provision of services by Medicaid/EPSDT.

SUDDEN INFANT DEATH INFORMATION & DISSEMINATION

Question: You're requesting level funding for the SIDS program. Do you feel as though this program is accomplishing what it was meant to do?

Answer: Yes, we feel that the program has made definite strides in accomplishing what it was intended to do.

In 1980 the SIDS Program will support 34 projects whose primary purposes will be to assure that the cause of an infant's death is confirmed by autopsy, to inform parents promptly about the cause of their infant's death, to provide counseling services for the family survivors, to educate those health safety and personal care providers about SIDS and related issues, and to inform the public about SIDS.

At the Federal level the program has published and disseminated informational and educational materials as well as produced and distributed audio-visual materials on SIDS, its effect on families and methods to assist the survivors.

Contract activities have been supported which result in materials that are useful in the service grant projects, or which contribute to the identification of agencies and organizations which may be mobilized to initiate SIDS services.

Question: How many people, families are now being reached?

Answer: In 1978, the Sudden Infant Death Syndrome Program supported 34 service grants in 32 states. Approximately 4,350 families have project services available. Twenty-six states receive Federal support for SIDS projects to provide statewide services for approximately 3,775 families who annually lose infants to SIDS. In addition, six other states receive Federal support to provide services in portions of their states. An estimated 575 families have comprehensive and coordinated services available to them in these States.

Our 1980 budget request of $2.8 million will continue support of 34 projects which will make available information and counseling services to an estimated 4,350 families in 1980.

TRAINING IN MATERNAL AND CHILD HEALTH

Question: By reducing the training budget for maternal and child health, are you, in effect, saying that we have enough people trained in this important area?

Answer: There continues to be a need for well trained health professionals in programs serving mothers and children. The reduction in the training budget reflects a desire to apply more resources to other priorities such as services.

EFFECTIVENESS OF MCH TRAINING PROGRAMS

Question: What data is available to indicate the degree of effectiveness of maternal and child health training programs?

Answer: No formal studies have been done. However, subjective evidence indicates that the training programs are effective in terms of the numbers of people receiving training and education and the positions held. For instance, 80 percent of the physicians trained in the University Affiliated Centers training program go back to work in MCH projects, including State programs.

REDUCTION IN RESEARCH AND TRAINING

Question: Your biggest budget cut comes in the area of research and training. In fiscal year 1979 it was $32 million. In fiscal year 1980 you are requesting less than $15 million. What impact will this have on your training programs across the nation in terms of the number of people trained?

Answer: The number of training programs will be reduced by one-half. This means that 3,470 health professionals will receive training in 1980 compared to 6,938 in 1979.

Question: How many research grants programs will have to be reduced?

Answer: Forty research grants will be terminated in 1980.

Question: Where will those programs find new funding?

Answer: A few research programs may find partial support from private foundations and Federal research grants programs. Most, however, because of their "continuation" status will find it difficult to secure new sources of funding. Moreover, a large number of the projects to be terminated are in the applied health care area and Maternal and Child Health and Crippled Children specific, and thus may not be of much interest to other agencies.

RESEARCH AND TRAINING CENTERS

Question: What impact would this budget request have on university-affiliated facilities and pediatric pulmonary centers?

Answer: The number of such programs will be reduced by one-half. University-affiliated facilities will be reduced from 21 to 10, while pediatric pulmonary centers will be reduced from 11 to 6.

Question: How did you end up at a level of $14.8 million intead of some other level, say a more moderate phaseback of $20 million or even $25 million?

Answer: The funding level for the Research and Training program was a result of budget constraints and a decision to place a higher priority on funding for health service delivery programs.

Question: What will the impact be of the funding level you have proposed both on the number of children to be served and the number of health professionals to be trained?

Answer: Both the number of children served and the number of health professionals trained will be reduced by approximately one-half.

RESULTS OF RESEARCH

Question: Do the results of the maternal and child health research efforts merit the cost?

Answer: Very much so. The need for MCH research is for well designed studies of the delivery of health services to mothers and children, and of ways to improve the provision of services to them. Research into ways of reaching high-risk populations of mothers and children, cost of health care to children, and the outcome of health care are only some of the research areas being looked into.

Question: Can you give some specific examples of how these research efforts have paid off in the past?

Answer: Some examples of research projects include a research study to improve teenage contraception practices, restoration of function to congenitally deformed hands, and interpartum intensive care and outcome of the infant. The number of patients/users of Title V Maternal and Child Health and Crippled Children's programs likely to benefit from the currently supported projects range from anywhere between one-hundred thousand to several millions. Because the prospective findings have applicability to settings other than Title V programs, the prospective pool of beneficiaries likely to benefit from these research projects can be multiplied by a factor of 5 through 10.

PROGRESS IN GENETIC COUNSELING

Question: Since the Committee initiated the Genetic Information and Counseling Program two years ago, what impact has there been in terms of outreach activities and the development of State and regional genetic programs?

Answer: Twenty-one State-wide genetic testing, counseling and information project grants have been awarded to 21 separate States. In addition, through cooperative arrangements with these States, 9 additional States receive at least partial coverage. The genetic State-wide Systems program will provide services to 630,000 people and counsel 378,000 people. In addition, 22 sickle cell projects provide screening services to 183,000 people and counsel another 22,000 people. Also, in 1980, 25 hemophilia centers will serve a total of 2,500 patients.

Question: Can you give us some specific examples of education programs which have been developed?

Answer: There are several examples of education programs which have been developed. For instance, the National Clearinghouse for Genetic Disease Information has been established, sickle cell films have been produced, and laboratory training programs have been started at the Center for Disease Control in cytogenetics and hemoglobinopathies.

Question: How many areas will receive programs with funding level of $10.6 million?

Answer: Of the 56 States and health territories in existence, 44 States and health territories will have some type of genetic disease program, whether it is a genetic State-wide system, a sickle cell clinic or a hemophilia treatment center.

Question: How many areas would this leave without Genetic programs?

Answer: Only New Hampshire, Delaware, Kentucky, Arkansas, Oklahoma, North and South Dakota, Hawaii, Nevada, Virgin Islands, American Samoa and the Trust Territory are totally without coverage. In addition, parts of Wyoming and Montana are covered by Colorado's genetic system and parts of Idaho and Alaska are covered by Washington's genetic program.

Question: Chairman Magnuson considers this Genetic Information and Counseling program one of the best prevention programs that we have. Would you elaborate a bit in terms of how you feel about the program? What its potential is? And where you envision its going a few years down the road?

Answer: In implementing the Genetic Diseases Act, it has been this Agency's strategy to use the resources made available under the law to build a national Genetic Disease program, using existing State and Federal access points and provider capability to support and strengthen Statewide and regional systems, including local public and private resources and facilities. Under our plan for a national program, the coordination and linkage of existing health care delivery systems, such as maternal and child health, crippled children, hemophilia centers and sickle cell clinics, as well as entitlement programs like Medicaid and Supplemental Security Income, are basic to the implementation strategy. The development of State and regional laboratory capability is also supported by our Agency under Title V, as well as under the Genetic Diseases authority. Epidemiological assessment and surveillance is an integral part of the National plan for genetic diseases because it helps to assure that the program is responsive to the unmet need for genetic services. These activities are presently being supported by this Agency through an interagency agreement with the Center for Disease Control. Through this agreement, our Agency, in cooperation with CDC, defines the areas where State and regional

genetic systems need assistance, while CDC provides the technical expertise.

We believe that this program has considerable potential for expansion. There remain many people in the country who require genetic screening, counseling, and treatment and services should be expanded to provide them these services.

Question: What provision is being made to establish the advisory panel mandated by the National Genetic Disease Act Amendments of 1978? The Senate report stipulates that members should represent many disciplines, including physicians, lawyers, genetic counsellors, mental health professionals, research scientists, and others, and that they should meet no less than quarterly. Has this been instituted?

Answer: Procedures for the establishment of the advisory panel are well underway. A charter has been drafted outlining purpose and functions of the panel. In addition, we have already identified potential members and alternates to the advisory panel. We also have developed cost estimates and are currently working with the committee management offices to complete the final necessary arrangements.

Question: What requirements are being made in the Genetic Disease program for informed consent?

Answer: A requirement is included in the regulation that medical records and information must be held confidential and not be disclosed without the individual's informed consent, except as may be necessary to provide services to the patient or to provide for audits by the Secretary. Thus, such information as laboratory findings is considered an integral part of providing services to patients and, therefore, it would be unnecessary for laboratories to obtain informed consent prior to releasing appropriate information to providers.

GENETIC INFORMATION & COUNSELING

Question: You are requesting a $3.6 million supplemental request for Genetic Information and Counseling which will bring the total for fiscal 1979 to $10.6 million and you are requesting that same amount for fiscal year 1980. What new programs and services will you be able to initiate with basically a continued level of funding?

Answer: The 1980 budget request of $10.6 million will continue the same level of services as in 1979. This budget request includes $4 million to support 21 State-wide genetic systems which will serve 630,000 people and counsel 378,000 persons. It will also include $3 million to support 25 hemophilia centers which will serve 2,500 people. Finally, $3.6 million is included in our request for 22 sickle cell screening and education clinics. These clinics will screen 183,000 patients and provide counseling services to 22,000 people.

Question: A supplemental request of $3.6 million is for sickle cell programs. Wasn't this previously done in the National Heart, Lung, and Blood Institute?

Answer: Yes, the supplemental request of $3.6 million, plus an additional $183,000 to support the staffing and administration of the sickle cell program, was the same amount that was previously provided to this Agency through a transfer from the National Heart, Lung, and Blood Institute. The supplemental request proposes that these funds now be directly appropriated to the Health Services Administration.

HEMOPHILIA TREATMENT CENTERS

Question: Please describe to the Committee what your rationale is in terms of the lack of a budget request for the Hemophilia Treatment Centers programs in fiscal year 1980. How many programs were being funded under this authority?

Answer: Included in our 1980 budget request for Genetic diseases is $3 million for the Hemophilia Treatment Center program. The $3 million will support 25 hemophilia centers which will provide services to 2,500 people.

Question: How many people are they serving?

Answer: The 25 hemophilia centers presently in operation will be serving 2,500 people in 1979 and the same number of people in 1980.

Question: What is the total need or population in the United States which could utilize the services of a hemophilia treatment center if such services were available?

Answer: A recent study funded by the Bureau of Community Health Services indicated that the number of hemophiliacs in the United States in 1976 was approximately 18,000 to 19,000. We believe that the majority of these hemophiliacs could utilize the services of a hemophilia treatment center either in the center's catchment area or in the area of association with other health care providers.

COORDINATION

Question: The Committee last year in funding this program also mandated that the Center for Disease Control work closely with you. Could you tell us what is being done in that area and what are you doing to ensure that you are coordinating all your efforts with the Center for Disease Control as well as the genetics program at the National Institutes of Health?

Answer: We are working very closely with both the Center for Disease Control and the National Institutes of Health. For instance, we have developed two interagency agreements with CDC. One deals with the conducting of epidemiological assessments and

surveillance of genetic diseases, providing technical assistance to States to assist them in implementing the program. The second coordinated activity deals with laboratory standardization. Laboratory standards, proficiency testing and bench training for a variety of tests for genetic conditions which are being developed through this joint BCHS/CDC effort.

In June 1976, the National Institutes of Health established the genetics coordinating committee. This committee presently includes membership from our Agency and the Center for Disease Control. This committee works to promote a total coordinated effort in the areas of genetic diseases among all Public Health Service genetic activities.

FAMILY PLANNING

Question: Family Planning also has a supplemental request of $10 million which will bring the program to a level of $145 million for fiscal '79 and you are again requesting the same amount for fiscal year 1980. Given the Administration's emphasis on planning programs for pregnancy, isn't this in reality a very small budget request considering the total problem at hand?

Answer: Although the Administration is requesting a maintenance level for the Title X program in fiscal year 1980, the President's Budget includes $60 million, requested by the Office of the Assistant Secretary for Health, to support the Adolescent Health Program authorized under Titles VI-VIII of the Health Centers and Primary Health Care Act. Appropriations under this authority will provide health and support services to adolescents to reduce the number of unplanned initial and repeat pregnancies and provide care for those teens who do become pregnant and who subsequently become parents. The President's concern for adolescent health and pregnancy is still very strong; this can be clearly exemplified in many other Federal programs such as the Community Health Centers program and the Maternal and Child Health program.

Question: If you were to add up all of the money being put into pregnancy prevention programs, such as Health Centers, Mental Health Centers, Family Planning Centers, Rural Centers and in Maternal and Child Health, what would the total figure be?

Answer: The Bureau of Community Health Services estimates that its programs will utilize approximately $200 million for family planning services in 1980.

UNMET NEEDS FOR FAMILY PLANNING SERVICES

Question: How many people in the United States are being reached through Family Planning Programs?

Answer: In 1979, through all family planning programs funded by Federal, State and local governments and nonprofit agencies, an estimated 4.5 million persons will be served, 1.7 million of whom will be adolescents.

Question: How many low-income and high-risk clients are not reached at the requested level of Federal support?

Answer: We believe that there are presently 9.9 million low income and adolescent women at risk of unplanned pregnancy. Through all organized family planning program clinics 4.5 million people will be reached in both 1979 and 1980. An additional 1.5 million low income women including teenagers will receive services from private physicians. This means that there will be approximately 3.9 million low income and high risk women not being served.

Question: How many clients, especially teenagers, have received family planning services in the past year?

Answer: During the past year, 3.5 million persons received services through programs funded under the Title X program. Of these 1.4 million were adolescents. However, in total, family planning projects funded by Federal, State and local government and nonprofit agencies provided services to an estimated 4.5 million people, of whom 1.7 million were adolescents.

Question: How many more will receive services in fiscal year 1980?

Answer: Our 1980 budget request will maintain services at the 1979 level.

Question: Are there any figures which will demonstrate the effectiveness of the Family Planning Program in terms of reduced teenage pregnancies or pregnancy rates among those who have received new counseling or services?

Answer: It is still too early in our efforts to evaluate the extent to which the special efforts in the area of teenage services has affected pregnancy and abortion rates. We expect to see the effects of our efforts in data developed by fiscal year 1981.

FAMILY PLANNING FUNDS IN HEW

Question: Why are you requesting a 1979 Supplemental of $10 million to increase Title X Family Planning projects to $145 million when there are millions of additional dollars available for this purpose in other HEW programs and at the State and local level?

Answer: Title X represents the major source of direct Federal support for family planning services, approximately 43 percent of the total amount spent. Nine percent of the balance comes from Title V, while Title XIX provides 11 percent of the total. Also Title XX represents 17 percent of the total Federal support, while State and local and patient fees account for 20 percent of the total. In addition, Title X supported clinics generate a major portion of the revenues collected by other sources.

Question: Is there any difference between the Title X projects and the other family planning programs you show in your justifications?

Answer: A Title X project grantee is any public or private non-profit agency receiving all or partial support under this authority. There are 235 grantee agencies supporting a service network of 5,125 clinics.

The organized family planning service program consists of all organizations that provide subsidized family planning medical services in clinical settings or through contractual arrangements with private physicians. Title X is the major source of direct support for organized service programs.

COORDINATION WITH NEW ADOLESCENT PREGNANCY PROGRAM

Question: Please tell us how you intend to coordinate your family planning program with the new Adolescent Pregnancy Program in the Office of the Assistant Secretary for Health. How do these programs differ?

Answer: The Family Planning program funded under Title X of the PHS Act will continue its emphasis on reducing the incidence of unintended adolescent pregnancy through the expansion of outreach education, counseling and medical services in areas with high teenage birth and abortion rates. Through the 5,125 clinics funded all or in part by Title X, medical exams, education, counseling, health screening tests, pregnancy tests and immunization services will be provided. Under the adolescent health services and pregnancy prevention provisions of P.L. 95-626, the Office of the Assistant Secretary for Health provides grants to help States and communities develop a far more comprehensive community program for adolescents which will develop linkages with community institutions such as schools, churches, social service agencies, family planning clinics and other health providers that can provide supportive services for adolescents. It is intended that these centers, through meeting a variety of needs of teenagers for social, recreational, legal, financial, and medical needs, will be increasingly effective in reaching larger numbers of teenagers and, through this outreach, larger numbers of teenagers will have access to family planning services. Examples of the types of services provided in these programs, in addition to the services provided in most Title X projects, are legal services, mental health, employment counseling, recreational services and day care services. Both the Title X program funded under the Health Services Administration and the new adolescent pregnancy program will be coordinated under the Office of the Assistant Secretary for Health by the Deputy Assistant Secretary for Population Affairs.

Question: Wouldn't it be more useful if that Adolescent Pregnancy Program was incorporated in the Family Planning Programs?

Answer: We feel that family planning services is only one of the comprehensive health and support activities authorized under the new legislation. The Adolescent Pregnancy program also provides a range of medical, social, educational and related services which are necessary during and following pregnancy. coordination of these activities can best be managed by the Office of the Assistant Secretary for Health and should be kept separate.

PROGRAM SUPPORT

Question: Dr. Lythcott, program support for the Community Health Services programs has grown gradually. There was $26.3 million in 1978, nearly $30 million in 1979, and now you are requesting nearly $35 million in 1980. Could you please explain to the Committee why such massive increases in program support are necessary?

Answer: The increases contained in the Bureau of Community Health Services program support budget are necessary to cover the costs of new positions, pay raise and other personnel related increases. More than 50 percent of the $3.4 million increase in the Bureau's program support funds between 1979 and 1980 is to cover the costs of new positions. Of the $3.8 million, $2.3 million is for the new positions. An additional $900 thousand of the increase is to cover increases in Standard Level User Charges and other services. The remaining $550 thousand is to support increased technical assistance activities for the Community Health Centers, including the Inner-City Health Initiative, and National Health Service Corps recruitment and placement activities.

LEGISLATIVELY MANDATED PAY INCREASE

Question: It is our understanding that the PHS hospitals and clinics are being made to absorb the legislatively mandated pay increase from their existing fiscal year 1979 budget. This amounts to nearly $12 million. It seems as though since all of this will have to come from the remaining two or three quarters of fiscal year 1979, it would mean dramatic reductions in essential expenditures for patient care, it would mean dramatic reductions in essential expenditures for patient care, equipment, programs, as well as a cut back in personnel. Is this fact true?

Answer: The total cost of the October 1978 pay raise to the Health Services Administration in fiscal year 1979 is $21.4 million of which $11.3 million is for the Indian Health Service and $10.1 million is for the Health Services appropriation. the PHS Hospital and Clinic activity is supporting $12.9 million of these pay raise costs through a direct absorption of $6.1 million, proposed reprogrammings of $3.1 million to the Bureau of Community Health Services and the Office of the Administrator, HSA, and a proposed transfer to the Indian Health Service of $3.6 million. The remaining pay raise costs are being covered through absorptions in other activities of $1.0 million and a proposed transfer of $7.6 million from the Health Resources Administration to the Indian Health Service.

The reduction of funds available to the PHS Hospital and Clinics will not prevent the System from continuing to provide a full range of health services to all eligible beneficiaries. However, planned expenditures will have to be curtailed or postponed. The second year of the three-year equipment replacement and technology improvement plan will have to be reduced to covering only emergency replacement of inoperative items in fiscal year 1979. The related deferred expense will be $5.0 million. Another $1.2 million in savings will be generated by operating at an average lapse rate of one percent. Savings of $2.0 million will be realized by the reduction of planned development of primary care, community outreach and ambulatory care programs. Finally, savings of $4.7 million will result from a reduction in the maintenance and repair to the PHS Hospital and Clinic facilities.

Question: Why haven't you asked for a supplemental request which would maintain those programs at the current rate and at the rate required by law?

Answer: In order to help contain rising medical care costs and reduce the inflationary impact of a large Federal deficit, a supplemental request for funds required to cover the October 1978 pay raise was not submitted to Congress. Instead, the funds necessary to support all pay raise costs for programs administered by the Health Services Administration have been made available within currently appropriated levels. However, the PHS Hospital and Clinic System will remain in compliance with the provisions of P.L. 93-155.

PUBLIC LAW 93-155

Question: Can you categorically state that all Public Health Service Hospitals and Clinics under your budget requests, both supplemental and in the fiscal year 1980 budget, will be in compliance with the provisions of Public Law 93-155?

Answer: Yes, sir. All PHS Hospitals and Clinics will be in compliance with the provisions of Public Law 93-155.

PHS HOSPITALS STAFFING

Question: It is our understanding that the Public Health Service hospitals have not been exempted from the 1.5 percent reduction of personnel. Can you explain why this is so, considering that these facilities handle a great deal of critical patient care activities?

Answer: The PHS Hospitals and Clinics have been exempted from the 1.5 percent reduction of personnel in order that patient care services will not be affected by the reductions being made elsewhere in the Department. There was a temporary restriction on hiring during the first quarter, but this action created only isolated problems since the system overall began the year at a level above its budgeted positions. The Division of Hospitals and Clinics has since received an end of year ceiling of 5,516 and relief from hiring restrictions.

PHS HOSPITAL AD HOC ADVISORY COMMITTEE

Question: Dr. Lythcott, now that the Secretary has received the Advisory Committee's recommendations on PHS hospitals, give us some specific examples of what is being done to implement these recommendations?

Answer: The PHS response to the recommendations of the PHS Hospitals Ad Hoc Advisory Committee encompasses three areas: improved planning; program direction and realignment; and cost effectiveness and reimbursements. The first initiative will improve internal program planning and link program development to resource allocation decisions. Facility plans are also being linked to area planning in cooperation with the local health systems agencies so that missions can be keyed to community needs, particularly services to the underserved. This effort began with meetings held at each hospital consisting of the Regional Health Administrator, the PHS hospital director, the executive director of the local health systems agency, and representatives of local and State governments. Based on agreements reached at these meetings, each hospital will develop a plan to align its program with community needs. All plans will be reviewed by the local health systems agencies and transmitted to the Secretary by August 1979.

Program realignment involves refocusing research at the PHS hospitals consistent with expanded emphasis on primary health care; evaluating training priorities in the system; restructuring the hospital and clinic patient advisory councils; implementing an affirmative action plan for the system; introducing productivity standards within the hospitals and clinics; and bringing increased emphasis to the direct primary care programs in the hospitals and clinics.

The final area deals with comparative costs and reimbursements. The Assistant Secretary for Management and Budget is studying the costs of direct provision of services as compared to the cost of health services in the private sector. This study will demonstrate whether the cost of direct Federal health care continues to be lower than such care on the open market. Concurrently, the Administrator of Health Care Financing Administration will be providing assistance to the hospitals to analyze the issues involved in third party reimbursements. A contract is being developed to obtain technical assistance for the hospitals in establishing billing and collection procedures to facilitate maximum collections for reimbursable services.

Question: Can these major changes be made in the PHS hospitals at the same time that dollars and personnel are being effectively reduced?

Answer: The budget request before you for F.Y. 1980 was developed to support the PHS Hospital and Clinic system at a level of operation that will meet or exceed the requirements included in Section 818 of P.L 93-155.

Certainly the administrative changes proposed in the report can be accomplished within the proposed resources. These changes include the development of plans, the refocusing of research and

training programs, the development of affirmative action plans to identify qualified women and miniorities as candidates for top management positions in the system, the restructuring of patient advisory councils, and the development of productivity standards. However, until the results of the cost study comparing private sector costs to those of the PHS Hospitals and Clinics system for providing health care and the implementation study investigating the actual steps needed to be taken by the system to fulfill the Ad Hoc Advisory Committee's recommendations are completed, total resource estimates cannot be developed.

PATIENT SERVICES

Question: Can you guarantee this Committee that no patient services or personnel would be cut back in fiscal year 1980 because of budget constraints under your proposed budget?

Answer: The request for F.Y. 1980 was constructed to meet or exceed the requirements of Section 818 of P.L. 93-155. It is recognized that a budget constructed under these conditions may not be adequate to support major programmatic realignments, but the patient care, training, and research needs of the system have been considered in developing the requirements.

Question: Please provide a breakdown of Public Health Service hospital and clinic workload from 1973 to 1978 analyzing trends and forcast future patterns.

Answer: The workload of the PHS Hospitals and Clinics has risen since 1973 in the key indicators of admissions and outpatient visits. Inpatient days and average daily patient load have declined, but this can be ascribed to program emphasis to decrease length of stay -- ALOS -- to a number closer to that experienced in the private sector. This has resulted in a 12.5 percent decline in ALOS and a marked improvement in utilization. This favorable trend in workload towards a shorter ALOS is enhanced by the overall rise in admissions during the period, thereby utilizing beds made available through reduced length of stay. Reduced length of stay in conjunction with increased admissions normally indicates an increase in service intensity and reflects a heavier workload.

The slight decline in admissions from 1977 to 1978 probably results from program modernization and renovation projects made possible by the fiscal year 1978 $35 million add-on by the Congress. These renovation activities required the closure of major patient care areas, including operating suites, in order to accomplish the construction work without endangering patient health and welfare.

Outpatient visits have shown a steady increase from 1974 to 1978. This reflects strong program emphasis on ambulatory care and the increased resources provided to the free-standing outpatient clinics during this period. Overall, the statistics reflect improved utilization, a change of emphasis towards ambulatory care, and a general increase in overall workload. This pattern is expected to continue over the next few years as the recommendations of the PHS Hospitals Ad Hoc Advisory Committee are implemented. A chart showing workload during the period is provided as an insert to the record.

[The information follows:]

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USPHS HOSPITAL AND CLINICS WORKLOAD

	Fiscal Years						
	1973	1974	1975	1976	TQ	1977	1978
ADMISSIONS	31,327	27,874	30,942	31,351	8,080	33,509	32,925
INPATIENT DAYS	604,208	555,981	581,539	575,553	139,946	562,341	541,758
AVERAGE DAILY PATIENT LOAD	1,655	1,523	1,593	1,573	1,521	1,541	1,484
OUTPATIENT VISITS	1,582,606	1,444,655	1,554,613	1,677,912	431,523	1,773,508	1,724,897
Average Length of stay (General hospitals and excluding newborn)	16.1	16.8	16.9	15.9	15.1	14.3	14.0

DEPARTMENT OF DEFENSE REIMBURSEMENT

Question: What would you think of the idea of mandating that the Department of Defense reimburse the Public Health Service for out-patient as well as in-patient services that are provided for the beneficiaries and active-duty and retired military and their dependents?

Answer: A Congressional mandate that the Department of Defense -- DoD -- reimburse PHS for services provided to active duty and retired military members and their dependents would benefit the PHS Hospital and Clinic system and help correct and inequitable system which has developed. In effect, the PHS subsidizes DoD in care of individuals whose care is properly a DoD responsibility. In theory the PHS receives a fair equivalent of health care services in exchange for those provided DoD. In fact, our largest primary beneficiary group, merchant seamen, is not eligible for care in DoD facilities. Thus the system favors DoD with its greater pool of beneficiaries.

The effect is enhanced by DoD enforcement of the requirement that CHAMPUS beneficiaries use uniformed services facilities within a forty mile radius of the beneficiary's residence. This rule further increases DoD utilization of PHS facilities in areas where non-Federal sources of care might be elected.

The report of the PHS Hospitals Ad Hoc Advisory Committee recommended that PHS facilities seek reimbursement from DoD for outpatient services rendered to DoD beneficiaries. This action would permit PHS greater access to overall resources and allow more financial flexibility in responding to the needs of medically underserved populations in a more responsible manner.

SOURCE OF REIMBURSEMENT FOR PATIENT SERVICES

Question: There are other ways in which the Public Health Service hospitals can become less dependent upon fluctuating HEW budget decisions. One we mentioned, Department of Defense reimbursement, seems to be a good route to try. However, it would also be worthwhile to have your comments relating to the PHS hospitals and their ability to collect Medicare, Medicaid and private third-party payments.

Answer: Third-party payments account for approximately 13 percent of the annual budget of the PHS Hospitals and Clinics with 10 percent to 20 percent of this amount coming from Medicare, Medicaid, and private third-party payers. The fiscal year 1979 reimbursement estimate is $23 million, an increase from $20.5 million in fiscal year 1978, reflecting a 10 percent to 15 percent annual rate of increase in such revenues. Increased revenues derive from additional Section 328 agreements serving patients with Medicare, Medicaid, and private health insurance coverage and improved hospital ability to collect these revenues. This demonstrates program emphasis to establish community ties that will serve the medically underserved populations who are the Department's concern.

The hospitals vary in their ability to generate revenue. Nassau Bay has a workload almost exclusively made up of primary and beneficiaries. Other facilities, like Staten Island, provide services to a broad community base which generates revenue.

Success in generating reimbursements depends on our ability to meet Medicare/Medicaid requirements and to recruit and train sufficient billing and collection staffs. In order to assure acceptable performance in this management area, the PHS Hospitals are presently developing a contract that will analyze our accounting and billing systems for adequacy in meeting third-party reimbursement needs. Subsequent recommendations for systems improvement are expected, with an objective of improving our ability to bill and collect funds and more accurately projecting these revenue sources.

MODERNIZATION AND IMPROVEMENT OF EXISTING FACILITIES

Question: What needs still exist in the various PHS hospitals and clinics for modernization of clinics or construction and improvement?

Answer: The Department submitted a $120 million plan for the modernization of the PHS Hospitals and Clinics to the Congress in January 1977. The plan detailed, in priority order, the work necessary to eliminate violations of fire and life safety codes, to achieve compliance with standards of the Joint Commission on Accreditation of Hospitals, to perform urgent facility repairs, and to accomplish renovation and modernization of areas to meet current standards of patient care. Primary emphasis was placed on patient safety, with secondary priority accorded to facility preservation and the achievement of operational efficiency. The $120 million plan was subsequently reduced by the fiscal year 1978 appropriation of $15 million and adjusted to reflect offsetting reserves and the addition of funds necessary to comply with Section 504 of the Rehabilitation Act of 1973 relating to the elimination of barriers to access by the handicapped.

Question: What would be the total amount required to do this properly?

Answer: Following the adjustments to the original $120 million plan to renovate and modernize the PHS hospitals and clinics, a revised requirement for $105 million existed. Subsequently, the PHS Hospitals Ad Hoc Advisory Committee recommended that the capital improvement plans of each hospital be revised in accordance with the review of the hospital's role by the local health planning agency. These reviews and resultant revised mission statements are expected to be completed by August 1979. At that time further adjustments in the expected cost of accomplishing the modernization plan may be expected. These costs will consider the continuing requirement to comply with the life safety, fire codes and JCAH standards, in addition to any costs associated with changes in policy direction. The base plan will probably remain substantially intact, but since many projections formerly planned could be impacted by the

Implementation Task Force report, definitive cost estimates cannot be provided until after August.

BUILDINGS AND FACILITIES

Question: You are requesting $3 million for Buildings and Facilities. Nothing was provided in fiscal year 1979. Please detail for the Committee exactly what this $3 million will be used for?

Answer: The $3 million requested for F.Y. 1980 will support the complete renovation of nine of fifteen buildings used to house resident patients, who do not require acute hospital care, at the National Hansen's Disease Center at Carville, Louisiana. A summary of the use of these funds is contained as an insert to the record.

[The information follows:]

Summary of Funds Request for Carville

Roof Repairs	$ 76,000
Interior Renovations	850,000
Plumbing Renovations	87,000
Electrical Upgrade	775,000
Central Air Conditioning	1,205,000
	$2,993,000

Question: Is it possible to hold payment of these programs over until another year?

Answer: In the normal course of construction programming, a lag of approximately six months occurs between the appropriation of funds and the completion of design. Normally, outlays of funds do not amount to more than 20% during the first year of a major project because of the planning process. Therefore, should Congress agree with this request and appropriate the funds, the actual dispersal of the majority of the funds would probably occur in early fiscal year 1981.

Question: In fiscal year 1978, your budget was $917,000 for lands and structures. In fiscal year 1980, you are requesting $3 million. Under what account does this fall and please give us an explanation of the program contained within this and how and why is such a large increase so necessary at this time?

Answer: The $3 million in question is contained in the buildings and facilities activity. The requested funds represent the first phase of a two phase program to upgrade the plumbing, mechanical and electrical systems, and to install central air conditioning in patient dormitories at the National Hansen's Disease Center, Carville, Louisiana. These quarters are 40 years old and have never had a major renovation. We believe that the safety and comfort for the patients of the Carville facility resulting from the planned improvements to the patient dormitories are of sufficient importance to proceed with the improvements in fiscal year 1980.

PAYMENT TO HAWAII

Question: As you know, the Committee has constantly provided small increases for the Leprosy Program in Hawaii. Again, in F.Y. 1980, you are requesting the same amount as was provided in 1979 -- $1.6 million. Given the tremendous rise of "boat" people coming to Hawaii from Southeast Asia, isn't Leprosy a new and real concern in that area?

Answer: The State of Hawaii has not projected an increased patient load for F.Y. 1980 based on the arrival of "boat" people from Southeast Asia.

Question: Should we be putting more money in and are more patients arriving with Leprosy?

Answer: Based on an evaluation of the patient load figures and the declining trend which they display, a constant Federal funding level of $1,600,000 in F.Y. 1980 seems to be appropriate.

Question: What is the match in terms of the State providing for this program as well as the Federal Government?

Answer: The fiscal year 1979 appropriation and the F.Y. 1980 request of $1,600,000 represents a Federal share of approximately 66 percent of the total program cost. The balance is funded by the State of Hawaii.

Question: Would you please give us a chart, breaking down for the last say, five years, what the patient load has been at the Leprosy Clinic?

Answer: We shall be happy to provide actual workload data concerning fiscal years 1974 through 1978 for the State of Hawaii's Hansen's Disease Program. An insert will be provided for the record.

[The information follows:]

Hawaii's Hansen Disease Program

Fiscal Year	Patient Days	Outpatient Visits
1974	53,139	2,001
1975	50,031	2,121
1976	46,314	2,206
1977	44,622	1,569
1978	43,373	1,396

FEDERAL EMPLOYEE OCCUPATIONAL HEALTH

Question: Would the $728,000 that you are requesting for Federal Employee Health programs be adequate in terms of absorbing pay costs and personnel requirements to continue these programs at the current rate?

Answer: The $728,000 will be adequate. The program will reduce administrative travel and consultant services in order to absorb $25,000 in pay costs. This should have no detrimental impact on the program.

BURN INJURY PROGRAM

Question: The 1976 EMS legislation authorized funding for a Burn Injury program. What is the status of this program at the present time?

Answer: The program is a three year prospective study to define the magnitude of the burn problem in the United States and to describe in detail the current burn care delivery capability. Phase III of the Burn Program will be funded on or about September 30, 1979. The contractors will complete their work and make final reports a year later. The preparation of the Department's Report to Congress on this demonstration program should be available in February 1981.

Question: What specific problems are being addressed and what concrete results can you report from this effort?

Answer: The purpose of the study, using six large regional areas, is to collect information and data describing how burn patients use the current resources available for burn care, to describe the financial status for the delivery of current care, and to conduct a limited number of applied burn care research and development tasks.

All associated research tasks are on schedule. These include a burn severity index, a burn nurse training curriculum, and evaluation of the "team care" approach to specialized burn care. It is too early to provide any specific results of these tasks.

Question: Last year while reporting that you had not implemented the burn injury training authority you acknowledged the shortage of training in burn care. Have you made any progress in providing assistance for training of physicians, nurses, and other personnel in burn care?

Answer: The Burn Demonstration Program is not providing direct training assistance to providers. The New York demonstration site, through the University of Rochester, is developing and testing a burn nursing education curriculum. This curriculum will be reviewed for its acceptability as a standard for burn nursing education. The Texas demonstration site is developing and testing a short-term burn nurse training course. These are the only training currently being supported by the Burn program.

Question: Last year, you reported that you were preparing a comprehensive description of the Nation's current burn care capability. Have you completed this study? What does it show?

Answer: Phase III of the Burn Program will be funded on or about September 30, 1979. The contractors will complete their work and make final reports a year later. The preparation of the Department's report to Congress on this demonstration program should be available in February 1981.

Question: What has been learned from the burn projects and what are the main accomplishments?

Answer: The main accomplishments to date include she development of a common patient care and financial data set, the completion of a common training program for data collectors, and the initiation of data collection for all burn patients from point of entry into the system through outcome. Projects have also initiated the collection of cost, charges, and reimbursement information for each burn patient. The quality control measures being used indicate 90 to 95 percent of the patients accessing the hospitals are being counted and tracked.

Question: Congress provided $42.6 million for Emergency Medical Services in fiscal years 1978 and 1979. You are proposing that we reduce this by $3 million to $39.6 million in 1980. What is your rationale for reducing this program which has been received wholeheartedly by most States and regions throughout the United States?

Answer: We are not reducing the Emergency Medical Services program funding. For the last three years, the appropriation for this program has included about $3.0 million per year for a study to assess the national burn care capability and develop and present to Congress a national burn care strategy. The Burn Injury program is now in the final phase and we will not require any additional funding for 1980.

STATE AND LOCAL SUPPORT FOR EMS

Question: How much money have State and local governments been putting into EMS Programs?

Answer: Our survey for fiscal year 1978 shows that $306,479,171 was provided from State and local government funds for the support of emergency medical services. This figure has increased significantly over the past four years. The detail of the funding received from non-Federal government sources will be provided for the record.

[The information follows:]

Emergency Medical Services
State and Local Government Funds

Fiscal Year	Source of Funds		
	State	Local	Total
1978	35,687,486	270,791,685	306,479,171
1977	30,914,371	234,346,879	265,261,250
1976	29,902,517	200,389,021	230,291,538
1975	19,846,273	189,744,871	209,591,144

Question: And what assurance do you have that these localities, States, regions will be able to and willing to absorb any increased costs?

Answer: I believe the steady annual increase in State and local support since fiscal year 1975 attests to the fact that they will continue to support emergency medical services at an adequate level of funding.

GRANTEE SELF-SUFFICIENCY

Question: Have any of the grantees completed their Federal assistance and become financially self-sufficient? If not, when do you expect this to start occurring?

Answer: Twenty-nine emergency medical services regions have completed their funding as of June 30, 1978. In addition, we plan to fund 37 more regions for their final year with fiscal year 1979 money. To the best of our knowledge all of the currently completed regions are operating a level comparable to or higher than that achieved during support under title XII.

Nevertheless, we hope to further strengthen their fiscal position through a concerted technical assistance effort. We have contracted with the University of Pennsylvania to conduct a limited case study. We have not yet received the report, but we intend to use the results to strengthen our technical assistance to States and regional emergency medical services organizations on how to improve and develop the regional base for continuation after the grant program.

EMS ADMINISTRATION

Question: We have received reports, unconfirmed thus far, that a departmental internal reorganization is removing the EMS program as a separate entity from HEW regional offices. In other words, in the past, one or two persons in each regional office were devoting full time to coordinating grant activities in the EMS program and now you are planning to eliminate these positions and include the administration of the EMS program at the regional level with other health activities. Is this true?

Answer: No, this is not true. Although a reorganization is taking place, relative organizational placement of the Emergency Medical Services program remains unchanged. However, should a particular problem come about as a result of the reorganization, we shall act to resolve it immediately.

Question: Apparently there is a great deal of concern among grantees across the country that the success and effectiveness of the EMS program to date has depended to a great extent on the individual attention the program has received at the regional office level.

What exactly are your plans in regard to administration of the EMS program at the regional office level and what is your rationale for changes if changes are to be made?

Answer: The Emergency Medical Services reorganization at the regional office level is but one part of an overall reorganization plan by the Public Health Service. The basic change that would effect the Emergency Medical Services program is a relocation of the program from the Division of Health Care Systems to the Division of Health Services Delivery. This move is a mandated action directed by the Office of the Assistant Secretary of Health to insure that programs at the regional level will be administered by the same organizational component as at the headquarters level. Staff currently providing Regional Office emergency medical services consultant services will be relocated to a different Division and will continue to provide the high level emergency medical services technical assistance and operational support as in the past. We feel it is in the best interest of all concerned that the current Regional Office emergency medical services team continue to provide full-time consultant services for this complex and well regarded program.

EMERGENCY MEDICAL SERVICES PHASEOUT

Question: Explain the three-year phaseout and the overall impact of terminating the EMS program early?

Answer: The Emergency Medical Services program is time limited to five grant years per grantee. A major portion of the program has been completed and therefore consideration must be given to its phaseout. The three-year phaseout period, fiscal years 1980 through 1982, is designed to continue current grantees to a logical completion, with emphasis on basic life support. At least 25 percent of EMS regions will have completed advanced life support and an additional 58 percent will complete basic life support. Achievement of these objectives will significantly improve emergency care since initiation of the program in 1974. This improved level of capability will also provide the foundation upon which State and local communities can continue to improve Emergency Medical Services commensurate with their local needs and financial resources.

The need to implement the EMS concept in the 17 percent of EMS regions not achieving at least the basic life support level of capability will have to be met with State, local and other Federal sources of funding.

Question: At what stage will all projects be phased out by HSA and who will provide any remaining funding needed?

Answer: At the completion of projects funded in fiscal year 1982, it is projected that of the 304 regional EMS regions, 4 percent, or 13 regions, will not have participated in the grant program; 13 percent, or 40 regions, will have completed planning only; 58%, or 176 regions, will have completed the establishing and initiation or operations phase with a basic life support system, and 25 percent, or 75 regions, will have completed the

expansion and improvement phase with an advanced life support capability.

The possible sources of funding to provide the remaining financial support needed have to be State and local revenues, voluntary contributions, and other sources of Federal assistance.

The goal of the Federal Medical Services program is to establish 304 contiguous, financially self-sufficient regional EMS systems. This is to be accomplished through three types of project grants: (1) Feasibility studies and planning; (2) Establishment and initial operation; and (3) Expansion and improvement.

The program comes up for reauthorization in the 96th Congress.

Question: After six years of funding for this program, where do we stand in establishing this network of EMS systems?

Answer: With the award of grants for fiscal year 1979, the status of the 304 regional emergency medical services system development is projected to be: 4 percent no activity, 28 percent planning, 43 percent establishing and initial operations, 16 percent expansion and improvement, and 9 percent completed the program.

Question: How many EMS projects are there in each project grant category?

Answer: Following the award of grants in June 1979, we anticipate that 85 of the regional projects will be at the planning phase; 47 projects will be at the first year and 84 at the second year for establishing and initial operations; 9 projects will be at the first year and 37 at the second year for expansion and improvement. In addition, 13 regional areas will not have participated in the grant program and 66 regions will have completed their eligibility in the EMS program.

PROGRAM SUPPORT

Question: Again, there is a rather large increase in Program Support from $7.5 to nearly $9 million for fiscal year 1980. Specifically, what will this increase be used for and how many new positions are you requesting for the Public Health Service Hospitals program and how many will you be reducing from EMS because of your proposed budget reduction?

Answer: The largest portion, $838 thousand, of th $1.5 million increase will be used for the expansion of technical assistance required by Emergency Medical Services grantees. The remainder of the increase will be used to cover various mandatory cost increases, including within-grade increases, annualization of the October 1978 pay raise, and annualization of new positions. The largest mandatory cost increase is $325 thousand for Standard Level User Charges for the PHS clinics. No new

positions are requested for the PHS Hospitals. The budget contains a reduction of 24 EMS positions resulting from the proposed phase-out of the EMS program by 1982.

HSA POSITIONS

Question: Last year, both the House and Senate agreed to a specific number of positions for the Health Services Administration in a conference agreed-to bill. Would you please tell us if you have been given each of these positions and, if so, if they are all filled what your plans are for them?

Answer: The fiscal year 1979 Health Services appropriation contained a provision giving Health Services Administration 9,258 positions. This figure included 8,821 direct positions and 199 reimbursement positions for the Health Services appropriation, 66 positions allocated from the Bureau of Prisons and the Appalachia Regional Commission, and 172 positions for the Public Health Service Service and Supply Fund. Although we have been given each of these positions, about 300 of them were unfilled on January 31, 1979, and the impact of the Leach Amendment and the President's initiative to reduce Federal employment may mean that approximately 6% of administrative positions may not be filled this year. All positions budgeted for the Public Health Service Hospitals and Clinics and for the National Health Service Corps are expected to be filled.

Question: Dr. Lythcott, in all of the position increases throughout Health Services, how many new positions are being requested for the Health Services programs here in Washington, D.C., in terms of administration and overhead?

Answer: Five positions are requested for our headquarters operations.

Question: How many programs are being allowed new positions for use in the program components in the regions?

Answer: The Community Health Centers and the National Health Service Corps will receive new positions for use in the regions.

DOES HEW SYSTEM ADD TO PAPER WORK?

Question: Please explain the Management Information Tracking System (MITS).

Answer: The Management Information Tracking System is an internal Departmental management technique under which certain key objectives are singled out for special tracking. The principal steps to achieve these objectives are described in quantative terms and a specific date for their completion is stated. Periodic meetings are held with the Secretary to discuss progress in achieving these objectives.

Question: Will this add to the paperwork already required of small clinics?

Answer: The MITS is strictly an internal Departmental system. The relationship of an individual project or clinic to the MITS system is remote. The MITS uses data already being reported through the ongoing Bureau Common Reporting Requirements and therefore does not add to a project's paperwork. In fact, BCRR was instituted several years ago and attempts to consolidate and simplify previous reporting so that one compatable reporting system is used for Bureau projects instead of various unrelated reports.

Question: What is the estimated staffing time required to complete information on the MITS?

Answer: Individual projects do not spend any time completing information specifically for the MITS. However, we estimate that the projects will spend 40 hours per year on the Bureau Common Reportng Requirements.

Question: Does the administrative screen apply to both the large and small clinics?

Answer: The administrative overhead standard applies to all projects regardless of size.

Question: Is this equitable?

Answer: Yes, we believe that the need to maintain high standards of quality and productivity require that we be uniform in applying these standards to all projects. From the view point of the projects, there are some economies of scale in larger projects which might tend to spread overhead costs over a larger base. On the other hand, smaller projects can sometimes more easily control overhead costs. On balance we have not found that smaller or larger projects have any relatively harder time meeting the 20 percent administrative overhead rate ceiling.

Question: Does a 20 percent maximum administrative screen not unfairly penalize the small clinic with low medical staffing costs?

Answer: The problem that smaller clinics or projects have in meeting the 20 percent administrative overhead standard is that it sometimes takes a while for them to acquire their full complement of medical staff and begin providing services. However, administrative costs begin from the first day projects begin planning and development activities. To be equitable we do not apply the administrative overhead rate until projects have a chance to hire medical providers and begin operations which takes approximately 18 to 24 months.

MIGRANT WORKERS

Question: Is there any evidence that the existence of migrant centers is improving the health of migrant workers and their families?

Answer: Yes. For instance, 94 percent of the children seen in migrant health centers have received immunizations. Also 47 percent of the women 17 years old and over who are users of the migrant centers have received annual breast exams. In addition, annual pap smears have been provided to 47 percent of the women 17 years old and over served in our centers. I should mention that all these percentages are at least as good, and for the most part better than, the national average.

Question: Can we categorically point to this program and prove that infant and maternal mortality rates have declined as a result of the program?

Answer: No. The infant and maternal mortality rates for migrants have not been measured specifically. A categorical correlation of program efforts and decreases in these indices cannot therefore be calculated. The data that most closely approximates these indices for migrants are those collected for migrant homebase counties. These data indicate that infant mortality has dropped about 20 percent between 1966 and 1977.

Question: And what kind of health problems are most commonly found among migrants?

Answer: Some of the most common health problems found among the migrants are ear, nose and throat infections, pulmonary disorders, hypertension, gastro-intestinal/hepatic disorders, malnutrition and depression.

BUDGET INCREASE

Question: You are requesting $41.4 million for Migrant Health Centers in fiscal 1980, a sizeable increase over the $34.5 million allowed in fiscal 1979. Will the bulk of this new funding go for new centers or will it be used to supplement and expand existing services?

Answer: Our 1980 budget request for the Migrant Health Program will provide continued support to the 112 centers. The $6.9 million increase contained in our budget will provide services to an additional 33,000 migrants in 1980. In total, 590,000 migrants and seasonal farmworkers will be served in 1980. Thirty-three percent of the total eligible migrant population will be served by our 1980 budget request. Included in the $6.9 million increase is $690 thousand for the expansion of the migrant hospitalization program. In 1980, $4.1 million will be used by this program to provide hospital services to 3,800

people. Nineteen centers will participate in the hospitalization program in 1980, which is 5 more than participated in 1979.

Question: Are we now in a position where we basically have the migrant routes in the United States covered with adequate migrant health centers?

Answer: Generally, yes. This Agency has established a primary care project in virtually all migrant high impact areas. In addition, the Bureau of Community Health Services has about 500 projects in rural areas which are available to serve migrants. What is now essential is that these projects broaden their scopes of service and serve more of the migrants in their service areas. In other words, coverage is reasonably good, but penetration or outreach into the migrant population is still low about 30 percent. Penetration is now largely a function of the amounts of funds appropriated.

NATIONAL HEALTH SERVICE CORPS

Question: You are requesting a large increase for the National Health Service Corps from a level of $65 million in fiscal year 1979 to $81.8 million in fiscal year 1980. How many health professionals do we presently have out in the field in the National Health Service Corps?

Answer: As of January 1979, we had 1,467 National Health Service Corps assignees in the field.

Question: Could you give us a breakdown of how many of those are nurses; how many of those are dentists; how many of those are doctors, etc.?

Answer: Of the 1,467 NHSC assignees in the field 748 were physicians, 236 were dentists, 304 mid level practitioners and 179 were other health professionals.

GOALS OR OBJECTIVES OF THE CORPS PROGRAM

Question: To date, the National Health Service Corps has focused primarily on recruiting physicians for underserved areas. Do you feel that a more complete role in relation to the delivery of comprehensive care in the United States would be more desirable?

Answer: Yes, I do believe that such an expanded role would be most beneficial to the Nation's underserved. The National Health Service Corps is a proven, demonstrated way of bringing high quality health care to large numbers of people. Corps providers are well trained, motivated individuals who are able to provide health care in areas which are geographically isolated and to populations which are frequently poorly educated, minority

and low income. The experiences gained in such settings are invaluable. Additionally, the Corps and its orientation toward comprehensive, preventive primary care could positively impact on the disease oriented, crisis-directed care provided in many areas of the country.

Question: What should be the main goals, or role, or scope in your opinion of the National Health Service Corps program in the future?

Answer: The main goal of the National Health Service Corps should be to make high quality, prevention oriented primary care accessible to all residents, and particularly to disadvantaged, in health manpower shortage areas. The Corps should provide this care through primary care systems linked to secondary and tertiary services.

NATIONAL HEALTH SERVICE CORPS ASSIGNEES IN URBAN AREAS

Question: It is our understanding that under the expanded definition of medically underserved areas, urban areas are now utilizing more and more National Health Service Corps personnel. Several concerns have been raised over the fact that we have a long way to go in the rural area. Why start developing urban areas before we have hardly begun the task of covering rural medically underserved areas? Would you please comment on that?

Answer: Current and future National Health Service Corps involvement in both urban and rural areas will be significant. There are approximately 24 million people residing in primary care Health Manpower Shortage Areas, of which approximately 12 million reside in urban metropolitan areas. P.L. 94-484 directed the Department to designate urban as well as rural shortage areas, and to designate populations with access problems as well as geographic areas with availability problems, for the placement of Corps assignees. This results in placement of Corps professionals in urban areas such as New York City, which do not have an overall lack of manpower but which do have significant components of the population -- for example, the South Bronx, Brooklyn, Harlem -- with limited or no access to existing health services.

Although the number of Corps placements in urban areas will increase in the future, this will not result in neglecting rural communities. By the end of fiscal year 1979 there will be approximately 1,446 assignees in rural areas or 84 percent of the 1,725 Corps staff. Current projections indicate that there will be more than 3,700 assignees in rural areas by 1985.

LINKAGE WITH OTHER FEDERAL PROGRAMS

Question: What efforts does the National Health Service Corps Program take to coordinate and provide linkage between

other Federal programs, such as Rural Health Initiatives, Health Underserved Rural Areas, Community Health Centers, etc., and the private sector?

Answer: The National Health Service Corps is a major component of the Public Health Service strategy to integrate services and resources to develop county-community and multi-community primary care systems in areas identified as having health manpower shortages or severe medical underservice.

Today, Corps professionals are key providers of health services in other Federally supported programs such as Migrant Health projects, Community Health Centers, Community Mental Health Centers, Appalachian Regional Commission sites, Public Health Service Hospitals, Federal prisons, the National Hansen's Disease Center and Indian Health Services facilities. The Corps assignees also provide significant professional augmentation to State and local health departments where they assist States in their maternal and child health programs through their contributions to the Department's Improved Pregnancy Outcome projects.

Linkages with the private sector include: formal and informal agreements to provide NHSC assignees hospital privileges in area public and private hospitals; assignee participation in local professional associations; and assignee involvement in local community activities in and around their areas of assignment.

OPTIMAL NUMBER

Question: In your opinion, looking down the road, what is the optimal number of Corps personnel that you feel is necessary to adequately serve the medically underserved areas of the country?

Answer: There are approximately 23.7 million Americans living in 1,116 currently designated primary care Health Manpower Shortage Areas. A recent analysis indicates that there is a total need for 17,152 primary care physicians in shortage areas. By 1990, this need is expected to decrease only slightly to 16,400. We are beginning to meet the need with Corps assignees within the constraints of the National Health Service Corps manpower available to date.

In 1979, we will have 1,725 assignees in these areas; by 1980, we will have 2,820 assignees.

Question: How many of those are rural areas?

Answer: A total of 821 or 74 percent of the 1,116 primary care shortage areas designated are in rural areas. There are 23.7 million Americans living in the 1,116 primary care shortage areas, of whom twelve million persons or 51 percent reside in

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rural/nonmetropolitan designated areas. In 1979, 84 percent of the Corps staff will be assigned to these areas.

Question: How many of those are urban areas?

Answer: There are 295 or 26 percent of the 1,116 designated primary care shortage areas located in urban/metropolitan areas, in which 11.7 million persons, or 49 percent, reside.

NATIONAL HEALTH SERVICE CORPS SCHOLARSHIPS

Question: If you add the number of Corps personnel presently in the field to the number of people who are being presently educated under the National Health Service Corps Scholarship program, how many would that be?

Answer: The present number of Corps field personnel is 1,467. Scholarship recipients in health professions schools total 5,344, while an additional 2,447 are in deferment for residency training. Therefore, there are presently 9,258 people in the National Health Service Corps manpower pool.

Question: What specific relationship do you have with the scholarship program which is administered through the Health Resources Administration?

Answer: A formal interagency committee meets on scholarship policy issues on an as needed basis. Inter-program meetings on ongoing administrative issues are held each week, and we have found these meetings to be a very effective device for coordination between these two programs.

Question: It is our understanding that there is a very poor coordination in terms of policy and access and personnel between these two programs.

Answer: We do not believe that to be true. We feel that the regular weekly meetings of program people have resulted in markedly improved coordination between the programs. In addition to this regular meeting on administrative and policy matters, program personnel are in constant daily contact regarding individual deferments, placements, and other scholarship personnel matters.

Question: What would you think of either moving the Corps program to Health Resources or moving the scholarship program to Health Services?

Answer: Because the scholarship program is a manpower and resource planning program, it requires different skills and support systems than does the National Health Service Corps, which is a service program. I feel that the steps we have jointly taken to improve communication and program coordination have resulted in a smoothly functioning system and I would be reluctant to reorganize or move the programs unless I was

convinced that increased effectiveness or efficiency would be the result.

NUMBER OF PEOPLE BEING SERVED

Question: How many people are now being served because of the National Health Service Corps program who were not being served in the past?

Answer: Our 1980 budget request for the National Health Service Corps of $81.8 million will make it possible to provide services to 1.9 million people, while establishing a service capacity for almost 4 million people.

Question: How many people remain unserved because of insufficient National Health Service Corps personnel?

Answer: Our latest data indicated that there are presently 23.7 million people residing in primary care health manpower shortage areas around the country. Our 1980 budget will provide the capacity to serve 4 million people.

RETENTION

Question: Every year, we seem to be making more and more progress in terms of retaining Corps personnel at their practice sites. Would you please tell us what kind of progress you have made during the last year in terms of retention rates?

Answer: The National Health Service Corps retention rate includes persons who have established independent practices which they intend to maintain in health manpower shortage areas as well as persons who extend in the NHSC for a minimum of one year beyond their initial tour of duty. In 1978 the Corps experienced a 48 percent retention rate. While this was the same as the 1977 rate it reflects a 10 percent increase over the 1976 level. Although the percentages have remained the same for the past two years, the actual numbers of individuals retained have increased.

Question: Along those same lines, what types of support systems are most appropriate for Corps personnel in terms of services, personnel, and community resources necessary to maintain Corps people at their site?

Answer: There are various factors to consider in maintaining Corps personnel at their sites. The Area Health Education Center system is important in providing health professionals with continuing professional education and encouraging the regionalization of educational responsibility of health professional schools. A regional specific referral, consultation, and professional back-up system is essential for alleviating professional isolation and lack of peer association and communication. The cooperation of professional organizations

that support progressive health delivery models is a component of the latter system. Encouraging the use of physician assistants and nurse practitioners is an example of what is meant by progressive models. Community resources such as modern facilities, with adequate equipment, support staff, and a well conceived health care plan are prerequisites for attracting as well as maintaining professional personnel. The organizational structure of the delivery center and the cooperation of the community leaders can influence the practice plans of health professionals at their sites.

CORPS VOLUNTEERS

Question: Your justification states that 45 new volunteers will be assigned by the NHSC in 1980 and a limited number in 1979. Are you curtailing recruitment of volunteers?

Answer: The curtailment in the recruitment of volunteers will occur in 1979. Given the field strength of 1,725, we will have openings for 625 new openings in 1979, all of which are projected to be filled by scholarship recipients. However, we have continued a limited recruitment program of volunteers as a contingency to fill positions designated for scholarship obligees who buy out of their obligations and to fill additional vacancies created if more assignees terminate their service than we had estimated. Our current estimate of volunteer recruitment in 1979 is dependent on the number of scholarship assignees who buy out of their scholarship obligation, the number of assignees who terminate their service in 1979, and the number of volunteer assignees recruited in 1979 who may not actually enter on board until 1980 because of personal scheduling preferences. In 1980, given a field strength of 2,820 there would be a net increase of 1,095 new positions. Of these, 1,050 would be scholarship assignees and 45 would be volunteers. However, an additional 500 volunteers would be recruited to replace people terminating service. Therefore, a total of 545 volunteers would be hired in 1980.

PRIVATE PRACTICE GRANTS

Question: You are once again requesting $1 million for private practice grants in the National Health Service Corps. Chairman Magnuson and many members of this Committee were strongly against the establishment of this program last year. Please give us some examples of how you expect this program to work and how such a minor amount of money is going to contribute to the well-being of the Corps Scholarship recipients.

Answer: The private practice grant program allows the Secretary to make a one-time grant to a National Health Service Corps Scholarship assignee who has completed his period of obligation and has agreed, in writing, to remain in a health manpower shortage area. The grant will assist the individual in

meeting the costs of beginning the practice, such as acquiring equipment, renovating a facility, hiring nurses and other personnel, and acquiring accounting and professional record systems. This private practice grant program does not apply to Corps volunteers.

The grant, which will be $12,500 per year for a maximum of two years, will provide the incentive for the individual to continue to build upon the previous Corps experience in an assigned area and to establish his proprietorship practice in a health manpower shortage area.

The Committee should note that scholarship assignees do not receive bonus pay and that the salaries of scholarship assignees are not competitive with the salaries of non-government professionals. The scholarship assignee's savings during his period of obligated government service is minimal. Therefore, a grant for $12,500 per year for a maximum of two years will assist the former Corps health professional in establishing his private practice is a realistic incentive.

SUBCOMMITTEE RECESS

Mr. FORBUSH. I hope you mean 7 working days from receipt of the transcript.

Mr. LIERMAN. You will get it tomorrow.

Senator MATHIAS. So, we are talking about 7 days from now. We made it working days so that the weekend intervenes.

All right, the committee will stand in recess until 2:30 p.m. this afternoon.

Dr. LYTHCOTT. Thank you.

[Whereupon, at 11:30 a.m., Tuesday, February 27, the subcommittee was recessed, to reconvene at 2:30 p.m. the same day.]

(AFTERNOON SESSION, 2:30 P.M., TUESDAY, FEBRUARY 27, 1979)

CENTER FOR DISEASE CONTROL

STATEMENT OF DR. WILLIAM H. FOEGE, DIRECTOR

ACCOMPANIED BY:

BILL FORBUSH, DEPUTY ASSISTANT SECRETARY, BUDGET
BRUCE WOLFF, DEPUTY ASSISTANT SECRETARY FOR LEGISLATION, DESIGNATE
DR. DONALD HOPKINS, ASSISTANT DIRECTOR, CDC
JIM BLOOM, EXECUTIVE OFFICER
DR. TONY ROBBINS, DIRECTOR, NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH, CDC

BUDGET REQUEST

Senator CHILES [presiding]. This afternoon we will hear testimony on the President's fiscal year 1980 budget for the Center for Disease Control.

Your total budget, I understand, Doctor, is $312,835,000, an increase of approximately $43 million over what was provided in fiscal year 1979. I understand also you have one supplemental in immunization and we will want to cover that in this hearing as well. If you want to formally introduce your colleagues, we will be glad to have any statements you have to make.

Dr. FOEGE. This is Bill Forbush, from the Department; Bruce Wolff from the Department; Dr. Donald Hopkins, Assistant Director of CDC; Jim Bloom, Executive Officer at CDC; Dr. Tony Robbins, Director of the National Institute for Occupational Safety and Health.

With your permission, I would enter the opening statement.

Senator CHILES. The statement in full will be placed in the record.

[The statement follows:]

STATEMENT OF DR. WILLIAM H. FOEGE

Mr. Chairman and Members of the Committee: I am here to discuss the 1980 Preventive Health Services appropriation request. In my opinion, this budget request represents a significant step in the evolution of the Center for Disease Control in this Nation's effort to reduce unnecessary morbidity and mortality. It is significant in the sense that we are: 1) proposing some action programs that are long over due, and 2) because we are, for the first time, requesting some basic funding for preventive health programs in the States. The fact that we are requesting an increase of nearly $42.5 million in a year that is characterized by fiscal constraints and concern about the size of our government testifies to the growing recognition of the need to pay more attention to prevention. It is clear that preventive health services have been given high priority in the budget deliberations for fiscal year 1980.

Programs at CDC form the core of Secretary Califano's special prevention initiatives. I hope that I can convince the Committee that we must be making some new investments in prevention without letting our guard down in traditional areas. This budget request is the culmination of a long review process. In addition to the Zero Base Budgeting which forces priority setting at each successive level, I have been engaged for more than a year in a process in which we are reviewing what we are doing and seeking directions on where we should be going. The process involved a special AD Hoc Committee of outside experts who identified the causes of preventable morbidity and mortality and made recommendations concerning National priorities and the role, if any, CDC should have. The deliberations of the Committee are reflected in this budget. I would like now to discuss some of the key features of our plans for 1980.

Basic Preventive Health Programs

When Congress passed Public Law 95-626, it authorized, among many other things, a new program of formula grants to States for preventive health service programs. This new authorization is designed to provide assistance to State and local health departments in carrying out programs against one or more of the five leading causes of death in the State. In this legislation Congress has emphasized the need to reduce risk factors and other causative conditions as a part of our efforts to reduce unnecessary morbidity and mortality. Passage of this forward-looking legislation coincides with a growing realization that what people do or don't do can be a critical factor in maintaining good health. We have requested $18 million for the first year in order to permit the States to undertake the necessary planning and development of program structures upon which more substantive operations can be built in the future.

The basic preventive health assistance is complemented by the risk-reduction activities of our health education program. We are requesting an increase of nearly $2.5 million to undertake comprehensive demonstration programs to further the development and testing of effective approaches. Our current health education efforts are directed toward these major areas: school health, patient education, smoking and health, sex education, and personal choice/lifestyle projects.

Disease Prevention and Control Programs

The Center also provides financial and technical assistance to States for the prevention of specific diseases. We are asking that you continue our Venereal Disease Program at a constant program level so that we may keep the pressure on venereal disease in this country. We have seen a reduction in the yearly reported incidence of gonorrhea from increases of more than 12 percent per year to essentially level incidence in fiscal year 1978.

Immunization continues to be one of our most effective and cost beneficial prevention measures. We are requesting funds to support Childhood Immunization Program and an Influenza Program. The decrease in the budget is a planned reduction in our Childhood Immunization Program that is commensurate with a reduced level of activity following completion of the Secretary's intensive Childhood Immunization Initiative. We are requesting only those funds needed to maintain high immunization levels in the population. However, we are requesting a supplemental appropriation for 1979 for this program. The funds are needed to maintain a concentrated campaign during this last year of

the special Childhood Immunization Initiative. I must point out that our reduced request for 1980 is based upon our getting the required amount of funding during 1979.

We have also requested funds to continue the Influenza Immunization Program. In 1980, we anticipate that the States will be supporting 50 percent of the total cost of the programs that are directed toward high-risk individuals. The aim is to provide protection to at least 50 percent of the target population. Also, we are requesting a supplemental appropriation increase for fiscal year 1979 that would bring the program to the $15 million level. I believe we need to be immunizing our high-risk people each year, and, unless some other mechanism is found, we must carry out this responsibility through an influenza project grant program.

I am especially pleased to be requesting a substantial increase in our dental health program. Dental caries can be prevented, and fluoridation is an effective preventive measure that is highly cost beneficial. However, we are reaching about half of the people who could be benefiting. We believe that the highest priority for Federal assistance should be small communities under 25,000 in population. With the funds that we requested in 1980, we will be able to provide assistance in establishing fluoridated water systems in areas serving more than 3 million people.

Occupational Safety and Health

A major aspect of preventive health is the reduction of unnecessary death, disability, and illness that is associated with earning a living. The Center's National Institute for Occupational Safety and Health has the principal share of HEW's responsibilities for improving health and safety of the workplace. The bulk of the increase that we are requesting will be devoted to carrying out our research responsibilities under the Federal Mine Safety and Health Acts--similar to our general industry program under the Occupational Safety and Health Act. In addition, we are asking for funds to strengthen our health hazard evaluation activities, to increase our knowledge for occupational health and safety across the country, and for special work related to the effects of smoking in the workplace. I believe that high priority must be given to improved safety and health in the workplace.

Chronic Diseases and Environmental Hazards

In this facet of our operations, we are requesting funds that will permit us to maintain the Urban Rat Control and the Lead-Based Paint Poisoning programs at constant levels. These intergovernmental programs are well managed and are good examples of a cooperative approach to problems of our environment.

The budget shows a reduction in our Diabetes Control program. This reduction to the 1978 operating level should not be interpreted as an indication that this is a marginal program. To the contrary, we believe that this has been a successful program that holds the promise for significant achievements in preventing unnecessary progression of the disease. In my view, we have a good working model for the control of diabetes and other chronic diseases. It is my hope that in developing preventive health services programs under the prevention formula grant that States will be able to benefit from the demonstrated success of our Diabetes Control program.

We are seeking a modest increase in our Nutrition Program in order to improve State and local capacity-making capabilities for monitoring nutritional status of their populations--especially children.

Epidemic Services and Investigation

The Center undertakes a variety of infectious disease control activities covering a wide range of diseases. A few warrant special note:

1. Legionnaires' disease. The organism now has a scientific name Legionella pneumophila. We are continuing to work to develop faster and more effective diagnostic tests, to learn more about the way in which the disease is spread, and to train public health workers so that they can share what we do know.

Cases of Legionnaires' disease have occurred in nearly every State and appear to be seasonal in nature.

2. Hepatitis. At the Center's laboratory in Phoenix, Arizona, we are preforming some of the leading work on hepatitis. You each have a handout that lists the breakthroughs on hepatitis that can be credited to our Phoenix laboratory. I have mentioned this scientific effort not because we are asking for additional funding, but because we are proud of the laboratory's record and want to share its success.
3. Smallpox. The budget contains a reduction of funds related to smallpox. In essence, we are reducing to a minimum our resource investment, anticipating final certification that smallpox has been successfully eradicated from the planet. We will be maintaining a special smallpox laboratory. With the agreement of other Federal agencies and private laboratories, CDC will be the only laboratory in this country maintaining the smallpox virus. There will be no more than two other laboratories in the world that will have this virus.

Prevention Technology

In this area of our operations we are holding steady with our training efforts, bringing to a close our State Public Health Laboratory contract program. However, the most exciting prospect is the major expansion planned for a hospital infections control initiative. Hospital infections are a large problem in this country, but we can have an input in the foreseeable future as we develop and promulgate guidelines for infection control in hospitals. As hospitals implement these measures, we will begin to see significant returns on this investment in terms of less suffering and reduced costs.

International Health

I hope the committee shares my enthusiasm for the contribution that CDC can make to improving health in the world community. With the $5 million that we have requested, we will be able to work meaningfully with the World Health Organization on its expanded program for immunization, especially in Africa; in helping develop global epidemic intelligence service patterned after our own Epidemic Intelligence Service; and to devise ways to stop the current epidemic of yaws, the crippling disease which affects poor children in rural areas.

Buildings and Facilities

In addition to funds to operate and maintain the facilities that we own, we are seeking support for two very important projects. The first is the expansion and renovation of the Taft Engineering Center in Cincinnati to provide sorely needed space for our Occupational Safety and Health Laboratories. Secondly, we are seeking funds for laboratory and safety improvements in our Atlanta facilities. To continue to ask our employees to work with highly infectious agents, we must take some steps that are beyond what we have been able to do with existing resources.

Mr. Chairman, I believe that this is a responsible budget request that is neither overly expansive in light of the need for fiscal constraint nor unduly timid in light of the tremendous needs and opportunities for preventive health services in this country. I will be happy to answer any questions that you or the other members of the Committee have.

Thank you.

REQUESTED INCREASE

Dr. FOEGE. The fact that we are requesting an increase, emphasizes the point of prevention. Our budget this year reflects both an examination by people from outside the Government, and examination by the prevention people in this Department. I am going to concentrate on six or seven specific areas.

PREVENTION GRANTS

Last year Congress authorized a new program which provides prevention formula grants to States. Under this authority the States would set up programs aimed at one or more of the five leading causes of death in their State, and develop programs to reduce the excess morbidity or mortality. While this will vary somewhat from State by State, a general overview of the five leading causes of death in the United States is shown on the following chart.

[The chart follows:]

FIVE LEADING CAUSES OF DEATH U.S. 1976

	Rate per 100,000 population
Heart Disease	337.2
Cancer	175.8
Stroke	87.9
Accidents	46.9
Influenza and Pneumonia	28.8

Dr. FOEGE. We are requesting $18 million this year to help the States develop a planning process for prevention which would then result in an implementation program the next year.

In addition, we are asking for $2½ million for health education to help us demonstrate effective risk reduction programs.

Senator CHILES. What do you envision? What is the 5-year cost for this plan? Where will we go from the planning process? What will be the Federal Government's share in these funds?

Dr. FOEGE. The authorization for fiscal year 1980 is $20 million. The appropriation is $18 million. For next year the authorization is

$60 million, and the third year, $75 million. We see this as an entirely new area, and we think this demonstrates a significant commitment to prevention on the part of the Federal Government. I would expect that the States within 1 or 2 years would begin putting a large amount of their own money in. They tell us it will take 1 or 2 years to get into their own budget process. Our contacts with State health officers indicate they're excited about it.

Senator CHILES. Is there a matching requirement? In other words, when we go up to this $70 million figure, is there some requirement that the States be putting in a certain amount of money and what will the program be? I understand the planning. We are giving the States money to come up with some kind of plan. What will we be giving the States money for after the first year?

Dr. FOEGE. During the first year, in addition to developing a plan, they have to develop an implementation process. Then, when they are asking for money the second year, it will be for an implementation plan describing precisely how they will reduce mortality in one of these five areas.

For instance, the fourth leading cause turns out to be accidents and most of that is nonvehicle accidents. Most States do not have a program for nonvehicle accidents, and in fact, in the Federal Government, we have no centralized program for nonvehicle accidents. We expect many States will come forward with a plan on how they will reduce home accidents, and fatalities from burns and so forth.

In answer to the other part of your question, I do not think there is a matching requirement, specifically.

Senator CHILES. There is no matching requirement?

Dr. ROBBINS. No. I was the State health officer in Colorado, and we worked on this legislation with Members of the Senate, and I think I am correct there is no matching figure.

DISEASE CONTROL PROJECT GRANTS

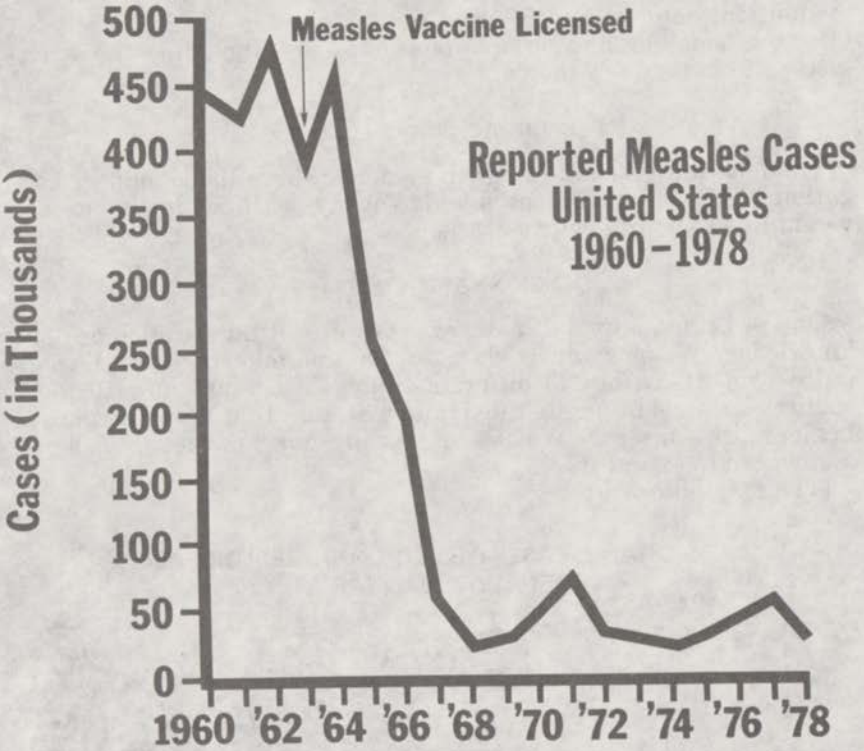
Dr. FOEGE. The second area in which we are asking for continuation of funds is grants to State and local health departments, in the traditional communicable disease areas.

For instance, venereal disease control and immunization programs. If you notice, we are asking for a reduction in the grants for the immunization programs; the reason being for the past 2 years we have been working on the backlog. We expect by October 1 to have reached 90 percent of that backlog and we can go to a maintenance phase. I must say the immunization program has been a real success. For example, last year there was a 53-percent reduction in the reported cases of measles in this country.

Senator CHILES. 53 percent?

Dr. FOEGE. 53 percent. While we were already at low levels compared to 15 years ago, this was unacceptably high for a country that has a vaccine delivery system.

[The chart follows:]



Dr. FOEGE. There was a 53-percent reduction in the reported cases of measles, a 22-percent reduction in the cases of mumps. Last year we only had 77 cases of diphtheria, which is an alltime low for the country. And only 82 cases of tetanus which means for 3 years in a row we have had less than a hundred cases of tetanus per year throughout the country. We believe the childhood immunization program has been successful.

We are also asking for funds to support a $15 million grant program for influenza. The objective is to reach 50 percent of the people at high risk. Also, we are asking for money in fluoridation. Fluoridation is the second best benefit/cost ratio program in all of the public health, and we are very happy with the fact we are asking for an increase of $4.7 million to institute new fluoridation programs which would reach about 3.4 million people during fiscal year 1980.

Finally, we are asking for continuation of grants in rat control and in lead-based paint.

OCCUPATIONAL SAFETY AND HEALTH

The third area in which we are asking for a major increase is money in occupational safety health areas. This is a major part of our overall prevention strategy. Most of it would be to carry out responsibilities in the Federal Mine Safety and Health Act, but some of it would be to increase our capability in health hazard

evaluation. Some would be used for research in looking at the ill effects of smoking and occupational exposure, including the synergistic effects between the two.

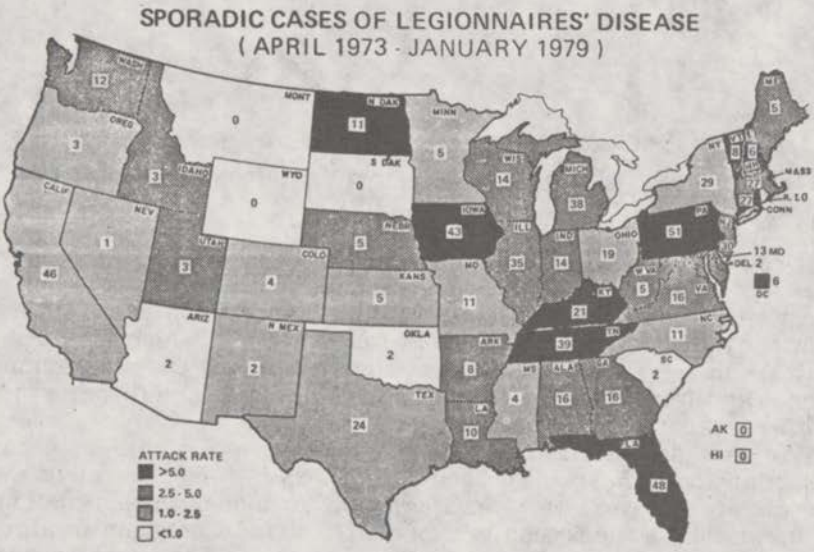
EPIDEMIC SURVEILLANCE

The fourth area has to do with epidemic surveillance and investigation. While we have done a wide variety of things in this area, I would like to point out two of them.

LEGIONNAIRE'S DISEASE

One is Legionnaire's disease, where we continue to increase our knowledge. We now have close to 500 sporadic cases of Legionnaire's reported from 43 different States. There are now 10 to 12 countries, in addition to the United States, that have diagnosed Legionnaire's disease. We are increasing our knowledge of when and where to expect it.

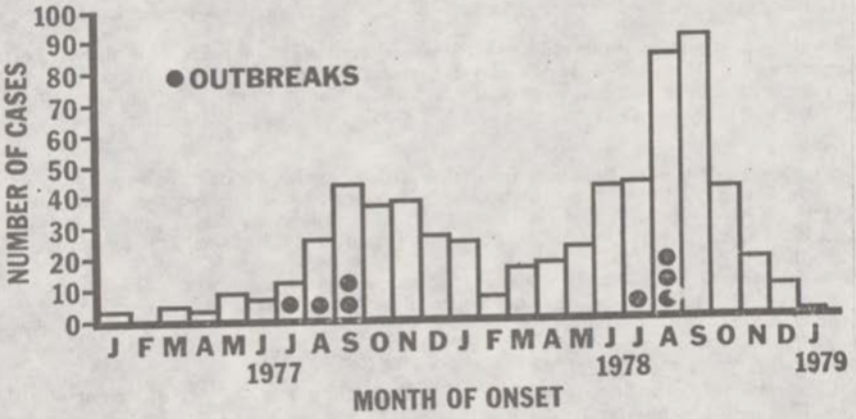
[The map follows:]



Dr. FOEGE. The next chart shows that we are having most of our sporadic cases as well as most of our outbreaks in late summer and early fall. We have, during the last year, repeatedly isolated this organism from water towers, cooling towers, and air-conditioners. We are not sure of the significance of this, however.

[The chart follows:]

Confirmed Sporadic Cases and Outbreaks of Legionnaires' Disease, by Month of Onset, United States, January, 1977 – January, 1979



Dr. FOEGE. This fall we had the International Symposium on Legionnaire's disease, and one of the things that came out of that meeting was the suggestion that we call this *Legionella pneumophila*, and it appears that the scientific community likes that name.

Senator SCHWEIKER. How does the Legion feel about it?

Dr. FOEGE. I think they have been in favor of this name.

HEPATITIS

A second area that is very interesting to us is hepatitis. In the handout there is a listing of the breakthroughs in hepatitis in the last year.

In the last year we have visualized with the electron microscope a third type of hepatitis which we are calling non-A/non-B hepatitis. For many years we believed that the hepatitis following transfusion was due to hepatitis B or serum hepatitis. It is now clear that 90 percent of all of these cases are non-A and non-B.

So we have had breakthroughs in finding a new type of hepatitis, breakthroughs in diagnoses of hepatitis, and now a breakthrough in the prevention of hepatitis.

We have a vaccine that has been tested in nonhuman primates. It has also been tested now in human volunteers, and this year we will test it in a larger group of people in five cities of the United States.

[The information follows:]

MAJOR MILESTONES REACHED IN 1978 BY THE HEPATITIS LABORATORIES, CDC

HEPATITIS

Non-A, Non-B

Accounts for over 90 percent of post-transfusion hepatitis.

Successfully transmitted to chimpanzees by inoculation of known infectious blood products.

Virus-like particles recovered from infected chimpanzee liver visualized by electron microscopy.

Studies initiated to develop serologic tests for diagnosis of non-A, non-B hepatitis which are essential for control.

Hepatitis A

Serologic test devised for serodiagnosis of hepatitis A using a single acute-phase specimen.

Preliminary metropolitan studies have shown that 40 to 60 percent of all cases of hepatitis A in the United States may be associated with day-care centers. (If confirmed, will lead directly to control of a significant amount of the infections in the U.S.)

Hepatitis B

The newly developed hepatitis B vaccine will be evaluated in a high-risk population in 5 metropolitan areas in the U.S. (If effective could prevent an estimated 15,000–20,000 cases of hepatitis B hospitalized annually among high-risk groups such as health care professionals, patients of mental institutions, and male homosexuals).

A sensitive test for hepatitis B "e" antigen, a serologic marker for determining highly contagious carriers, was developed. (This will help in interrupting disease transmission).

DIALYSIS DEMENTIA

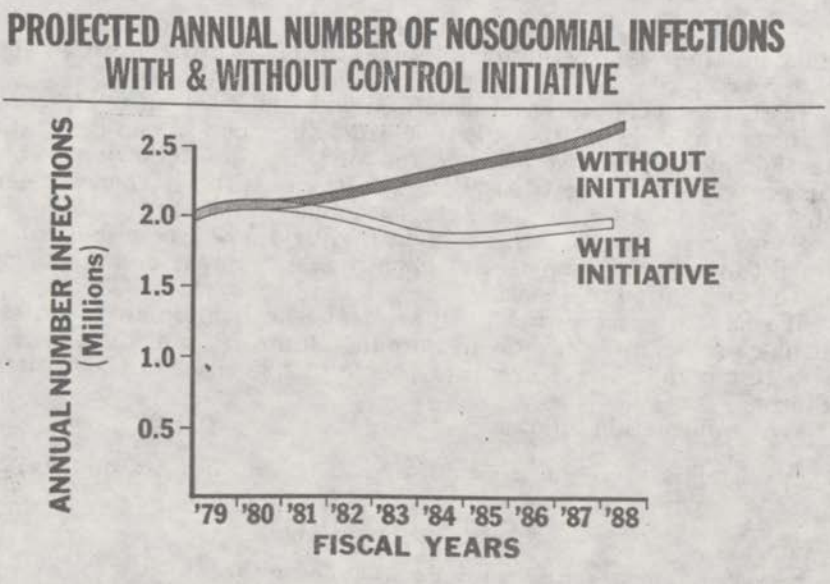
This relatively new disease is usually fatal and may account for 10 percent of all deaths of patients undergoing chronic hemodialysis.

Epidemiologic studies have shown that the disease is related to high aluminum levels in community water supplies. (Appropriate control measures can now be implemented).

HOSPITAL INFECTIONS

Dr. FOEGE. A fifth major area has to do with hospital infections. Two million times a year, we have people entering a hospital and acquiring an infection they did not have when they entered the hospital.

[The chart follows:]



Dr. FOEGE. It is costing us about $1 billion a year for these infections. About 20,000 people die directly from these infections and another 40,000 people die as an indirect result of these infections.

We are requesting an additional $3 million to promote an initiative which we believe by 1984 will reduce hospital infections, saving 12,000 lives and $150 million per year.

INTERNATIONAL HEALTH

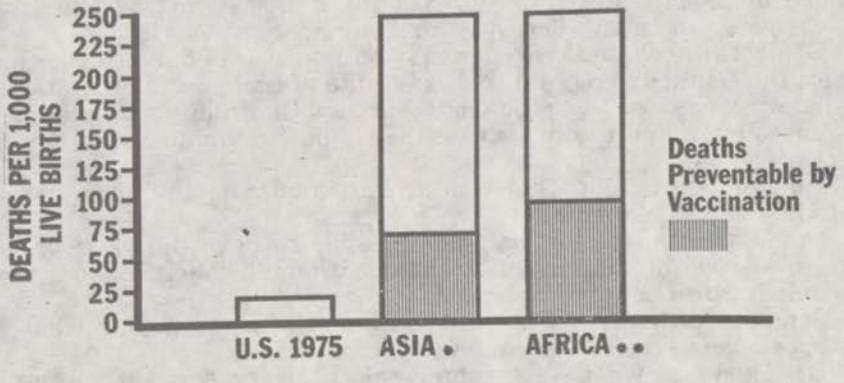
The sixth area has to do with international health. We are requesting $5 million this year primarily to extend to the world as a whole the experiences that we have had in the United States with the childhood immunization program. In the United States we expect that there will be about 20 deaths for every 1,000 children born, before the fifth year of life.

In Asia and Africa, there are about 250 deaths per 1,000 children born, or about 1 out of every 4 children born can be expected to die before age 5.

Of those 250 deaths per 1,000, someplace between 25 and 35 percent are caused by measles, tetanus, and disease that could be prevented by childhood immunization.

[The chart follows:]

Annual Number of Deaths of Children Under Five Years of Age per 1,000 Live Births



•Based on data from Bangladesh (Chen) & India (Simmons)

••WHO Estimates

Dr. FOEGE. We are suggesting a $5 million program to help the world health organizations in their campaign to have a program accessible to children by 1990 throughout the world.

Senator SCHWEIKER. If I may interrupt: We have earmarked up to $5 million in that field, and I just wondered, I knew we had some problems between the State Department and CDC in implementing it. I wonder where that stands at the moment.

YAWS

Dr. FOEGE. Of the $5 million in international health, while a lot of it will go for child vaccination, it will also go to a startup program for yaws. Dr. Hopkins can explain how the programs will go together.

Dr. HOPKINS. As you know, Senator, we have been working with AID and are preparing to send six persons to Africa next month. We are looking at the extent of the problem, looking at the sources that are available to deal with yaws in those countries, and finding what kinds of outside assistance is available.

Part of the problem in dealing with yaws is that it is not widely enough known. There has been little attention to this disease since the campaigns in the 1950's and 1960's.

Senator SCHWEIKER. What accounted for the problem? I thought you were trying to work out the redtape between what the State Department wanted and what I thought CDC people were saying, I just wondered what caused that problem, and has that been unsnarled yet?

Dr. HOPKINS. Well, we are working on, looking toward a meeting with your staff, and——

Senator SCHWEIKER. We are having a tripartite meeting between CDC, my staff, and the State Department; but go ahead; that is the problem.

Dr. HOPKINS [continuing]. AID. The problem seems to me, as I mentioned, many other people, not just AID, are not convinced that yaws is a serious problem. The general belief that this has been nearly eradicated is still in the background.

Senator SCHWEIKER. There is a difference of opinion about how much of an infrastructure you had to set up before you start a preventive program. Where does that stand?

Dr. HOPKINS. We feel very strongly on the basis of our experience with the smallpox program that it is quite possible, in communities where yaws is a severe problem, to go in with a minimum amount of investment and accomplish results similar to immunization program.

Senator SCHWEIKER. That was my intention, and I am sorry we are having trouble with it.

Dr. HOPKINS. We feel that it is possible to have the yaws program just as the immunization provided immunization services to people in rural poor populations.

Senator SCHWEIKER. What is the next step in untangling whatever is holding the whole thing up?

Dr. HOPKINS. We have got proposals being prepared to go out next month to West Africa. We are looking beyond that to putting one or two people initially in one West African country this fiscal year, and moving up to two or more countries in the beginning of fiscal year 1980. We are working with AID, to actually begin more of the yaws program, in the West Africa.

In addition to that we are looking toward a meeting in West Africa to be cochaired by, cosponsored by AID or the World Health Organization. We plan to bring in persons from other West African countries, present them with the data from the poor countries in which we are going to be working.

We have superficial annual reports from these countries now, but not a good, quantitative feel for the ratio between reported cases and actual cases.

Senator SCHWEIKER. My amendment really resulted from what CDC recommended or thought was a real need in this area, and I am a little disturbed that we went in and met honest and philosophical differences from the State Department, and I think the experts in this area.

I guess my question is: Do we normally have this kind of a problem with what CDC sees and where we get a State Department role, which would take a little different, philosophical or more dramatic approach?

Dr. HOPKINS. I think, in both of the meetings, with the yaws program and the expanded program on immunization, we have differing opinions on how fast we can go. In fairness to AID there have been some problems with the number of overseas stations they have, in developing a plan of operation before they can actually begin to implement the program in the country, very philosophical differences as well as, what you call bureaucratic problems, simply stages that they have.

Senator SCHWEIKER. Thank you.

BUDGET INCREASES AND ABSORPTIONS

Senator CHILES. Dr. Foege, last year's conference report specifically earmarked $2.5 million to increase the nutritional status program. I personally held out for the $64 million for these investigation and control in order to accommodate that increase, along with the $1.2 billion for fluoridation and salt by the chairman, and $1 million for diabetes.

Your justification shows only $1.7 million of your total level of nutrition. In 1979, we derived a $2.5 million level from materials submitted to us by CDC. Why aren't you following the direction of the Senate committee in the report, in allocating the funds in the budget?

Dr. FOEGE. We got ourselves into a problem of having to absorb pay costs, and having to reduce a number of items. We did reduce from 2.7 to 1.7 in nutrition. We were actually increasing from a base of only $500,000. Rather than cut programs that were already spending at some fixed level, we cut from programs that were being increased.

And I think that we have partially offset this by being able to get more support from the States so that they put more into the nutrition surveillance program.

This is one area that has been promising, so we have expanded the program, even though we did in fact reduce the amount that we intended to spend or wanted to spend.

Senator CHILES. From what you are saying, you have taken the pay raise absorption out of a few selected programs rather than through the cost of attrition; and that seems to contravene the intent of Congress, specifying increases in particular programs.

And I know you are not the only one who has done that. HEW has done that across the board. They picked programs they wanted

to take the cuts out of and left a lot of their favorite programs untouched.

I don't believe that that at all was the intent of Congress in saying the pay raises would be an absorber of themselves, nor do I think it is the intent of Congress when we go in and fight like hell in the conference committee and determine what a level of something is to be, and even when it goes over the President's budget—and we had a big fight on this with the House, and we ended up compromising, putting $1 million in for diabetes, and $1.5 million for fluoridation, and the $2.5 million that I was holding out for nutrition; and to turn around and find out that is the money used to absorb the pay raise increase, that is really sort of contravening the direction, I think, of Congress.

Dr. FOEGE. I recognize that. We have always had problems with knowing whether or not to cut everything at the prorated level. If we do that, we in fact disturb quality in many areas.

Mr. Bloom has something to add.

Mr. BLOOM. We did absorb about $1 million across the board in terms of savings in travel and savings that occurred with the personnel freeze that we were under this year. All this amounted to about $1 million absorption in addition to the nutrition cut.

Senator CHILES. I look at your items, where is that table there, and I see item after item, which is not cut at all. Formula grants, nothing. Projects grants, no cut, venereal diseases, immunization, no cut. Rat control, all those are very good programs. There is some attrition, I would assume in those programs, like there is attrition everywhere else, but to turn around and select the areas were you are going to make the major cuts, that doesn't sound like what Congress is talking about you doing.

If this is going to continue, and I assume it's been going on awhile, maybe we are going to have to write in the appropriation bill that these cuts be made on a pro rata basis, and if that is the intent of the Congress.

What would the effect of that be in the HEW progam?

Mr. FORBUSH. It's now pro rata, in the sense that costs are proportionate to the amount of staff for each appropriation. But if each part of the appropriation must absorb a pro rata share, it would be hard.

Senator CHILES. That is a problem maybe with having to write that in, but, I think you are certainly contravening the intent now when you select a program that you just decide you want to whack it, maybe a million bucks, and you are going to take it out of there and not touch other programs, you might get us something in writing, if you want to, as to what you see the effect of that language being, because I think you are going to get something like that in this bill, if this continues.

You are only going to spend $1.7 million of that effort in nutrition.

Dr. FOEGE. That is what is currently planned.

Senator CHILES. Well, you're 4 months into fiscal year 1979, I would hope you take a look at that and determine whether you are going to follow the intent of Congress which was, as I say, a fought-out situation in which we said we want to spend $2.5 million in that area.

Dr. FOEGE. We will take a look at it. This is an area I am interested in. I would hate to see cuts.

NUTRITION SURVEILLANCE

Senator CHILES. I certainly am too, that is why I fought to put the money in. One of the specific justifications for increasing the nutritional surveillance was to expand the system from 15 to 20 States. Do you anticipate meeting that goal and how many States, which States will begin to participate?

Dr. FOEGE. Yes, we do, Mr. Chairman, in fact, we are about to the 20-State level, and we intend to go beyond that in 1980 to 25 States.

Senator CHILES. How long do you anticipate it will take to get 50 States? I assume that much of that cost can be done at the same level of funding, because you had been pulling people out of the State. As you go out of the State, you ought to be able to rotate your personnel.

[The information follows:]

NUTRITION SURVEILLANCE EXPANSION

I am reasonably confident that complete geographic coverage by the Center of Disease Control (CDC) Coordinated Nutritional Status Surveillance System can be achieved in 3 years. This goal is being aggressively pursued, but some significant constraints must be recognized. First, expansion to include additional States depends on the desire and the capability of individual States to participate in the system. However, we have been effective in demonstrating the benefits to States which currently participate of having these data for program planning and evaluation.

Second, mechanisms must be defined to enable CDC to provide funds in some instances to assist States in basic administrative and data processing costs. This is also true concerning the acquisition of equipment for improvement in data quality. Finally, expanded geographic coverage will depend on how effective CDC can be in helping each State develop its inherent capacity to manage a nutrition surveillance system. This includes expertise in data processing and analysis.

Dr. FOEGE. We have gone from 18 to 20 States in recent months. We plan to go to 25 States by next year, and I think in the next 3 to 4 years, that we should have the program in all 50 States.

Mr. BLOOM. One of the difficulties is going to be that when we got our start, we got going in States that had the wherewithal to find some of their own funds and get going.

From this point on we are going to have to help support those that get added to the system. As ones we have helped can find the way to sustain their programs, then we will be able to move on to pick up on the next ones.

Senator CHILES. Give me some idea, if you will, of what you anticipate the additional cuts are going to be and some kind of schedule for that to take place.

[The information follows:]

NUTRITION SURVEILLANCE RESOURCES REQUIRED

We believe these things can be achieved with the requested resources and expect that most States will be participating by the end of fiscal year 1982. Specifically we expect 10 additional States in fiscal year 1980 and 10 additional States in each of the succeeding fiscal years. Sixteen additional positions and $2.7 million will be required in fiscal year 1980, seven new positions and $0.5 million increase in fiscal year 1981, and minimal increases thereafter.

Dr. FOEGE. We should also point out it is not just the geographic expansion, we have last year gone from a nutritional surveillance program of primarily children to one now that is children and pregnant women and also trying to attempt to define high-risk groups, so that we are doing both functional and geographic expansion simultaneously.

Senator SCHWEIKER. On the same point, I know what Senator Chiles is talking about; it was 2 years ago they did the same thing to me on diabetes. It was before you came to the Center, Dr. Foege, so it doesn't apply to you, and I want to make that very clear. But it's very frustrating for a legislator who acts in what I consider good faith, and picks a modest amount out for a $2 or $3 million program, No. 1, and then also exercises legislative restraint by not mandating, and we are also importuned not to mandate, so you have flexibility.

No. 1, we are the good guys. We put a small amount in the budget, not a big amount, and No. 2, we don't mandate, and I got whacked a couple of years back the same way Senator Chiles did. This puts us in the position where we have to mandate and index everything or do something that the Senator suggests, which I am very prone to do, because those of us who act with restraint and try not to impose on you folks really get short-changed by the process.

I really suggest you look very seriously at the principles somebody in the Department is following, because it's a repeated characteristic. It was done before.

The result is, if you are a small enough program, you get the ax. Sure you can do that, you can ax a small program, and I understand that, but it's really frustrating. I think continuing to follow this policy of just zapping the little programs puts us in a position where we have to come in with some kind of a limit, such as Senator Chiles suggested. We have acted with restraint and not tried to impose straitjackets on CDC.

But we obviously will begin to look at doing exactly that in view of this, because when you zap a small program, you zap it all. If you cut back a big program 1 or 2 percent, it doesn't have quite the impact. So I hope you will give his concerns some consideration, because I think it's a policy that gets this committee to the point where we no longer want to act with restraint and no longer want to let you manage within an open-ended way. If we are going to end up every year with the same procedure. I just put it on the table, because I think we are all going to have to take some action that makes us play a role we don't really want to play.

Senator CHILES. The rationale of a zero-base budget in having the absorption within that is that everybody takes a little cut and that little rationale, which is supposed to be a cornerstone of this administration is changed completely where you turn around and say, "Let's find a few programs that are favorites, and let's chop them and not touch the others."

One of the key parts of the comprehensive nutritional status monitoring systems is pulling together data from all the different health services programs. What specifically have you done to make data for medicaid screening and the Whitfield programs and the

maternal and child health care programs to make them compatible with your surveillances?

Dr. HOPKINS. As you know, we are working very closely with the Department of Agriculture in developing national surveillance systems for nutrition.

We have worked through the——

Dr. FOEGE. Let me interrupt. One of the pieces of evidence that we are, in fact, trying to come up with standard information is that we have now some new growth charts for the United States, that were developed by CDC and NCHS. These have become the standards throughout the country in just the last couple of years. In fact, they have now been adopted by WHO as the global standards.

This has been a fine effort. Instead of everyone having their own standard against which to measure whether people are malnourished or not, we now have a single standard we use for the entire country and the world.

Senator CHILES. Have all of the programs adopted these charts?

Dr. FOEGE. I think it's almost universal now. There are a few places that are still using other standards, but by and large this is becoming the standard and particularly in the 20 States in which we are working.

Let me also say, Mr. Chairman, that one of the nice things about the program, is that it's not only aimed at standardization, but simplicity as well.

We have come down to a few anthropometric measurements rather than having a large battery of laboratory tests, clinical findings, and dietary history.

We are able to say on the basis of a few things, such as length for age, weight for age, weight for length, a few anthropmetric measurements, whether a child falls in or out of the normal range.

SMOKING AND HEALTH

Senator CHILES. In spite of years of efforts, millions of Americans still smoke and thousands of young people start smoking every year.

Congress voted additional funds last year for the undertaking of new programs in smoking and health.

Report to us on your progress on these initiatives, including your efforts to reach preteens, women, and minorities.

Dr. FOEGE. It should first be noted that there has been a reduction in the smoking rates for the country as a whole. Secretary Califano reported these last month in the press conference. I think this has been very notable, and is particularly notable for certain groups, especially medical groups.

I think we have seen what happens to smoking habits through medical education. Physicians, who 30 years ago had the highest smoking rate of any occupational group in the country, have gradually gone down to 21 percent of the physicians that smoke. We have now, in our own program in the area of smoking and health, developed a monograph on the relation to smoking and occupational exposure. This is being made available to unions, to industry, and will be put out as a current intelligence bulletin within the next few weeks.

In the area of health education, we have been working in a number of areas. One approach is through school curriculum. It is called the Berkeley model, which is now being used in 400 school districts starting in kindergarten to seventh grade. It involves smoking and other aspects of health behavior. The American Lung Association has now developed a curriculum being used from kindergarten to third grade which we are also supporting.

In addition to this we are providing $3.5 million in grants to the States to develop their own health education programs. Most of this is in the area of smoking. In 1980 this will go up to $4.5 million.

Finally, we are emphasizing a wellness program, in not only schools, not only in industry, but in places where health is delivered, hospitals, through health departments and so forth.

We started with our own employees at CDC and have offered to them a computer-based appraisal of their own health. Once they see how they compare in longevity possibilities with other Americans, they have been given the option of signing up for Smoke-Enders clinics, for weight reduction clinics, exercise clinics, and so forth. We decided if we did not do this with our own employees, we would not have a very good chance of selling this program to other work groups. We have been doing a lot in the area of smoking. We intend to keep doing a lot. The main reason being, that there is no other area in public health where we can have such an impact on morbidity and mortality. It is the single most important cause of mortality.

Senator CHILES. What became of the National Clearing House for Smoking?

NATIONAL CLEARING HOUSE FOR SMOKING

Dr. FOEGE. That now answers to Secretary Califano, and the Surgeon General. We transferred 12 positions and $2.5 million of our 1979 budget with the National Clearing House. We helped them develop this at the Washington level to serve all the Public Health Service agencies.

Senator CHILES. There seems to be a growing fragmentation in the smoking program. You have some in the Assistant Secretary of Health, some in the Office of the Secretary, smoking programs of the Cancer Institute. Now, smoking programs in the Center for Disease Control.

Dr. FOEGE. I believe Mr. Chairman, what this demonstrates is how pervasive the smoking problem is in all of public health. One clearinghouse at a departmental level has provided coordination that we have never had before in the Public Health Service. There are many different ingredients but I believe this approach can work. The centralized cooperation has improved.

Senator SCHWEIKER. First, Doctor, I have some questions on flu, but since you and I have covered this on the Health Committee, I will just put these in the record for you to respond to, so this committee also has a picture on it. OK?

DIABETES

We did hold, after our diabetes hearing in the Health Committee a couple of questions that pertained to appropriations. How much in terms of physicians and funds do you think is needed for CDC to do a good job in this area? How much have you requested? How much have you received for the diabetes programs in fiscal 1978, 1979, and 1980?

Maybe one at a time. I hit you with too many. How many physicians in terms of funds and physicians are needed in this area?

Dr. FOEGE. The answer to that will be determined by decisions on how large the program should be. If by 1980 we would have a program with 10 States in phase 2 and 2 States in phase 1, and if we were to totally implement the recommendations, it would require a total of $4.4 million and 24 positions.

Senator SCHWEIKER. Totally implemented would cover how many States?

Dr. FOEGE. If we went beyond this to the recommendation of the Advisory Board, the program would include 12 States in phase 2 and 8 States in phase 1. This would require about $7 million this year and 34 positions. The Department, in answer to your next question, requested $2.6 million and 34 positions.

Senator SCHWEIKER. And that is fiscal 1980 you are talking about? And that compares to what for fiscal 1979?

Dr. FOEGE. In the present year we have $2.6 million and 34 positions, the DHEW requested level of funding in fiscal year 1980. However, the request before you has a reduction of $1.1 million from that level.

Senator SCHWEIKER. And the appropriation would allow for no new States to be added in 1980?

Dr. FOEGE. That is correct. Two more in 1979 and none in 1980.

OCCUPATIONAL SKIN DISEASES

Senator SCHWEIKER. Last year we got some testimony about occupational skin diseases. In response we asked HEW to report on the nature and extent of the problem and what is being done now in terms of research and prevention and submit the report and your recommendation for Federal program changes in time for this appropriation cycle.

My question is, Doctor, what is the status of that report on occupational skin diseases?

Dr. FOEGE. We did, in fact, develop the report, and we have a report in the phase of being cleared. I will ask Dr. Robbins to elaborate on it.

Mr. FORBUSH. It was submitted to the committee this week.

Senator SCHWEIKER. Is there any particular highlight or emphasis that you might want to state at this point? I realize we will have time to go over the whole thing, but anything in particular you want, any observation about the report you might want to make this afternoon?

Mr. FORBUSH. No, sir. I'd like to ask Dr. Foege to talk about it, and the scientific conclusions.

Dr. ROBBINS. It reviews the problem more completely than it's been reviewed before and lays out the areas for needed research and as you know, in terms of the number of workers effected by skin disease. It is probably most prevalent as a kind of occupational disease.

VENEREAL DISEASE

Senator SCHWEIKER. Your budget requests $32 million for venereal disease programs, the same amount as allowed in fiscal 1979 and 1978. How many people in the United States are expected to receive help from venereal disease programs?

Dr. FOEGE. As you know, venereal disease is the most common reported disease in the United States, with about 1 million people reported as having gonorrhea this year and perhaps 2 million or more actually having the disease. About 20,000 people were reported as having primary and secondary syphilis. The gonorrhea area of the program allowed screening of about 8½ million people for gonorrhea. Of this number, 397,000 were found to be positive. I would guess that most of the 1 million people reported are benefited either directly or indirectly by this program.

Senator SCHWEIKER. When you say indirectly, what do you mean?

Dr. FOEGE. The fact that the Federal program has allowed States to develop a standardized venereal disease program even if Federal Government money is not involved in doing the test. The fact that there is a Federal Government program has increased the attention the States are giving.

Senator SCHWEIKER. You are saying 8 million people are being directly or indirectly affected?

Dr. FOEGE. In gonorrhea. In syphilis it is more difficult to tell, because we have such a huge screening program. About 45 million people had a serological test done, but only 20,000 to 25,000 people had a new syphilis infection. Most of the serological tests being done are not done through the Federal VD program. Most of them are paid for by medicare, medicaid, or Blue Cross/Blue Shield as a part of a routine test in the hospital or clinic. But for the 20,000 to 25,000 cases of primary and secondary syphilis, there are always several people who are traced back from this case, and interviewed to see if they have syphilis. So I would guess over 100,000 people are affected directly in the interview process.

Senator SCHWEIKER. The 1 million gonorrhea victims treated directly or indirectly represents what percentage of those you estimate possibly have gonorrhea?

Dr. FOEGE. I believe it's 50 percent or less. We believe that there would be an additional 1 million cases of gonorrhea that did not come to our attention. This does not mean they're not treated; oftentimes they're treated by a private physician who chooses not to report them.

Senator SCHWEIKER. What about the same question on syphilis?

Dr. FOEGE. In syphilis——

Dr. HOPKINS. I expect because we have serological tests, you know, pick up routine serology, I would say that in more cases you will find that it's less than 100 in every case of each of the ones we find.

Senator SCHWEIKER. Hasn't our experience been that with a level or with a reduced budget we see a resurgence of VD?

Dr. FOEGE. I think in general that has been true, that when we allow complacency in any way, there's been a resurgence in cases. We certainly see this in special areas, that disease resurged because of lack of interest.

OTHER SEXUALLY TRANSMITTED DISEASES

Senator SCHWEIKER. Along the same lines, your budget expresses an interest in sexually transmitted disease other than syphilis and gonorrhea. What are these diseases and in what magnitude are they occurring?

Dr. FOEGE. Generally, people have thought of a few veneral diseases such as gonorrhea, syphilis, and chancroid. Now we are coming to realize there are a whole host of sexually transmitted diseases including hepatitis B, including herpes virus, which we are concerned with because it may be a cause of cancer of the cervix and including something we call nongonorrheal urethritis. Nongonorrheal urethritis is more common than gonorrhea, but is not reportable. It is made up of a number of organisms, not a single organism, a variety of organisms that causes this, but it's more common than gonorrhea. And in all of this, we have the very sad problem that while people often do not take gonorrhea very seriously, some 40,000 young women under 25 each year are becoming sterilized because of gonorrhea. It's a large health problem.

IMMUNIZATION

Senator CHILES. In fiscal years 1978 and 1979, we allowed $29 million for immunization programs and now you're requesting a supplemental of $20 million to bring that total to around $50 million for fiscal year 1979, and we see in 1980 your request drops to $33.5 million. Where do you stand on meeting the goals that you set last year?

Dr. FOEGE. Mr. Chairman, this should be broken down. The child immunization program and influenza are together, and it's in the child immunization program that we feel we are meeting the goal of reaching 90 percent of the children who are eligibile for immunization by October 1 of this year.

We have many States now showing on the school entry survey that they have reached 90 percent, some have reached 95 percent. Maryland, for instance, has reached 99 percent. So we have some very good examples coming in and we are projecting that for the Nation as a whole we will reach the 90-percent level by October 1. At that point we will go into a maintenance phase of trying to provide immunization for as close to 100 percent of all new children as possible. I believe it's been a remarkable success.

Senator CHILES. The figures did show that of the 52 million children 14 years old or younger, approximately 20 million have not been adequately immunized against childhood diseases, 34 percent have not been immunized against polio, 35 percent against German measles, 30 percent against measles, 24 percent against diphtheria, and tetanus—those figures are from the HEW statistics. How do we stand in that category?

Dr. FOEGE. Those originally came from the 1976 survey done by the Census Bureau. There was a repeat survey done last year that showed some improvement in these figures but not as large an improvement as we would have expected from the number of immunizations given. We are now going out to find whether this is a biased sample, whether parents if you ask them, how many immunizations has your child had, forget certain ones. We think the figures are much better than that at the present time.

Senator CHILES. You're proposing, would you let us know then when you get some, when you get a better determination?

Dr. FOEGE. Well, we plan to do a survey in September of this year, which we think should be not only a good history survey, but we will be taking blood determinations on a subsample to find out how many of them have actually been immunized against the particular diseases.

URBAN RAT CONTROL

Senator CHILES. Your budget for rat control for the third straight year is $13 million. How many new rat control programs in how many different cities will you be able to initiate. How many rat control projects will you continue to fund? In your opinion have you made any progress in the past 4 years in terms of rat control within the United States?

Dr. FOEGE. Let me make a couple of comments and ask Dr. Hopkins if he wants to enlarge. I think two areas are worth pointing out here. One, the amount of money that is put in by the Federal Government in the rat control program has gradually attracted outside money. When this first started several years ago, for every dollar put in the grant program it attracted another 25 cents from some other area. At the present time for every dollar put in the program, $3 is coming from someplace else, from States, from local health departments or from other Federal programs. Therefore, we have not increased the amount because we are attracting money from other areas.

The other thing is, yes, it has enlarged. We calculate some 6 million people now live in environmental areas that at one time had rats, that at the present time do not.

Dr. HOPKINS. I simply add in addition to attracting other money, we have been able to determine that in communities where rats are a problem, it costs approximately $600 per block per year to get those communities into rat-free status, and the communities then, when they pass that status, are able to maintain that status with the cost of about $37 per block.

Dr. FOEGE. Let me mention one other item, and that is the rat control program employs about 1,900 people. A thousand of those people or over 50 percent are local residents, people living in that area, and I think that's a significant development. In addition, over 1,100 people are employed using other Federal funds and Federal job programs such as CETA and community development.

Senator CHILES. Doctor, what percentage of our major cities would be under a rat control status and what percentage would not? I want to get some scope, in regards to the undone job, what is the upshot of what is left to do, and are we gaining or losing on it?

[The information follows:]

RAT INFESTATION PROBLEM

It has been estimated that 270 cities in this country presently have significant rat infestation problems. The program is presently providing Urban Rat Control services to 68 communities serving 5,032,000 target area residents.

Dr. FOEGE. We only work in 68 communities, and so we do not have as good figures as for these 68 communities, but I would be happy for the record to try to reproduce what we think would be the population of people in this country exposed at this particular time and what percentage of them are in programs.

Dr. HOPKINS. Another consideration here is that communities are required to go very carefully through the neighborhoods and where other areas in those communities are identified as rat-infested then the programs can move into these areas as well.

Dr. FOEGE. We can give you a rough estimate that for every community where we now have a rat control program, we believe there are two to three additional communities where there's no rat control program, but where they have rat problems.

Senator CHILES. Sixty-eight sounds like a pretty small number of cities, as far as determining it, where the rats might be.

Dr. FOEGE. That's right. And we know that there are many others, we try to cycle these funds in a sense that we close down a project once the local community has a program to keep it rat-free and then put the money into a new community. But we know for every one we are in, there are at least two or three others that have a significant problem.

Senator CHILES. Is every city that would like to apply for help in a rat control program, are you ever able to take care of them or do you have a waiting list, or would you say that you just have present clients, you can't deal with anyone else; what is the status?

Dr. FOEGE. We are not able to meet all the requests.

Senator CHILES. What would it take to meet the requests, and if you don't have that now, you can answer that.

Dr. FOEGE. We will be happy to provide that.

[The information follows:]

COMPREHENSIVE RAT CONTROL COVERAGE

The urban rat control program is designed to provide intensive support for a limited period of time to communities with a severe rat infestation problem that cannot be handled with existing resources. The Federal support provides sufficient funds to permit concentrated comprehensive activities to reduce rat infestations and to eliminate those environmental conditions that are conducive to rat proliferation. As the problem is reduced to a level that can be managed by the community resources, Federal grant funds are terminated. The funds are then used to support programs in other communities.

Although the program was not conceived to provide coverage to the entire nation, it is estimated that to carry out a concentrated effort in all areas of need simultaneously at least $60 million in Federal funds would be required each year for the next 5 years. This estimate is predicated upon local support for rat control activities remaining constant each year. In the projects that are underway States and communities are contributing $2 for every $1 of project grant funds. The overall cost of the program can be adjusted according to whatever degree of coverage below 100 percent is desired.

Senator CHILES. Under the present way we are going, would you say that we will ever get totally rat free as we have with the smallpox program?

Dr. FOEGE. I would rather try smallpox than rats. I believe it would be very, very difficult. It is clear, though, that this country was at one time rat free. The history of the rat is to follow people, and the rat did follow people moving west.

Senator CHILES. Before the white man got here?

Dr. FOEGE. I believe the first rats in San Francisco were reported in the 1840's.

LEAD-BASED PAINT POISONING CONTROL

Senator CHILES. Like many other project grant programs at CDC you are requesting basically a level budget for the third year in the row for lead-based paint poisoning. Why is this? Have your reports shown any decrease in the instance of lead poisoning in children across the United States?

Dr. FOEGE. Again, the amount of money we are putting in is attracting other money. For every dollar put into this program, we now figure on a dollar coming from some other source.

In answer to your second question, we are still picking up a large number of children with sufficiently high blood levels to require treatment. For instance, in 1979, we will screen 425,000 children and will find about 34,000 needing treatment.

But we are finding a reduction in the problem. For instance, in New York, looking at 1- to 5-year-olds, as recently as 1971, 80 percent of them had a lead level over 0.25 which we considered to be significant.

Using the same level now, only 20 percent have a level that high. We think there has been an improvement.

We believe the real problem in children may not be clear-cut mental retardation, it may be difficulty learning, and hyperactivity. We are convinced there has been a real improvement in 5 years.

Senator CHILES. Are environmental factors such as auto emission significant sources of elevated lead blood levels in children?

Dr. FOEGE. It is possible, under the right circumstances, to have elevated blood levels because of automobile exhausts, but in general, we have not found this to be a significant problem. And our real problem with children is because of lead-based paint not because of auto emissions.

Senator CHILES. Looking at the fact that there is no increase for rat control, venereal diseases, lead-based paint poison prevention, do you think this makes sense from both a fiscal and a social standpoint or is this a fiscal decision?

Dr. FOEGE. I believe that in the area of venereal diseases, we may be at the threshold where we are barely controlling the number of cases. I think in the last 3 years, we have reached a static figure of about 1 million cases of gonorrhea, which says to me that the amount we are putting in is controlling this.

The purchasing power of the dollar, though, is going down. I am concerned that we are walking a tightrope.

For lead-based paints and for the rat programs, I believe that the amount of money we are attracting from other sources is allowing us to do an increasingly good job in those areas by calling in increasing money.

SMALLPOX

Senator CHILES. Is it safe to say now that smallpox has been eradicated from the face of the Earth?

Dr. FOEGE. You are talking about the disease and not the virus?

Senator CHILES. Yes.

Dr. FOEGE. There has not been a known case of naturally occurring smallpox since October of 1977. There has been a laboratory accident in England since that time with two cases.

We will do as WHO is doing and we will say, after 2 years, with no natural cases, we are willing to call the world free, but I think internally we feel very comfortable that there is no chain of transmission of smallpox going on in the world today.

OTHER INTERNATIONAL AREAS

Senator CHILES. What other areas do you think it would be wise for CDC to get involved with throughout the world in developing countries?

Dr. FOEGE. This could really be divided into two areas. Are there other areas where we could have the same success as with smallpox? We believe there are others, yaws being one, and that is why we have put emphasis on yaws. We think that it is possible to actually eliminate that disease.

We think another area would be with guinea worm. The main areas afflicted by the worm constitute a significant economic problem because people are incapacitated at the beginning of the rainy season when they should be in the field. We believe this disease could be totally eliminated.

I don't know other areas where we could eliminate disease but we can do a significant job of controlling diseases by applying the same principles of surveillance and control. Knowing what the problem is. The main problem with yaws, the reason there is a disagreement of opinion, is because people are not using the same information. In Ghana in 1969 there were only 5,000 cases reported. Seven years later, there were 90,000 cases reported and the real number is probably much larger. But the surveillance is not sufficiently developed that everybody is using the same information.

We think it is important to support the WHO program, of childhood immunization, because this is something we can deliver, we have experience with it. We know it is a very quick and easy way to reduce childhood mortality.

Beyond that, we believe it is important to support the tropical disease research program of WHO because of the large numbers of people afflicted by malaria and other diseases.

And, finally, I would say the area of diarrheal diseases may be one of the most productive areas where we can work because simply changing the water supply that people have, can reduce tremendously the amount of diseases they have and the amount of mortality.

Senator CHILES. Do you have any idea what would be the relative cost of what we are talking about?

Dr. FOEGE. It is difficult to say.

Dr. HOPKINS. The problem anywhere is that providing safe water supplies is very expensive and there is a very small agricultural

output to those areas where people need safe drinking water. Therefore, we don't have good estimates of what the cost of the program would be.

Dr. FOEGE. We could say the smallpox eradication has cost the United States only $27 million, and that acted as a balance to attract money all over the world, some $300 million, spent on smallpox.

Therefore, we think if the United States would provide leadership in some of those other areas, the small amount of money could again be an occasion to gain money from the rest of the world.

OCCUPATIONAL SAFETY AND HEALTH

Senator CHILES. For nearly 9 months now, I understood that the National Institute of Occupational Safety and Health has been without a Director and I understand, Dr. Robbins, you have been appointed as chief.

What direction do you plan to take, and what do you consider to be your top priorities in carrying out these duties?

Dr. ROBBINS. Well, as you know, this is a research institute, we relate very closely with the needs of the Mine Safety and Health Administration and Occupation and Health and Safety Administration and Department of Labor, and that will remain one of our major priorities to provide good scientific guidance for these organizations.

In addition, we have a mandate to do training of professionals, and unlike the rest of the world of health professionals, occupational health professionals have not grown nearly as rapidly, and we still have problems in terms of training enough of these people, physicians, nurses, and industrial contacts and that is a continuing issue.

Maybe the most important thing that I find of interest is the need to improve our service function. In my mind, that is a longstanding tradition of doing health hazard evaluation, getting out in the field and trying to solve in a practical way the problems of workers getting ill, or getting injured, and we have been doing about 150 of these a year.

DIRECTION OF NIOSH

And, as you will see in this year's budget submission, there is a major increase approaching the $2 million, to increase the number and speed with which we deliver these health hazard evaluations. I see that as very important. No one doubts that occupational health is a tremendously important area, but if we don't deliver quickly, people wonder whether we take it seriously.

Senator CHILES. How many substances are you planning to test this year and how did you arrive at that?

CRITERIA DOCUMENTS

Dr. ROBBINS. I assume when you say testing, you are referring to criteria document developments. A lot of the Institute's effort and research which is done elsewhere, has been built into these criteria

documents, and there has been an effort to produce 24 a year in the past.

We will probably be doing fewer. We are moving slowly from single agents to looking at whole processes. Looking, for example, at pesticide manufacture and formulation rather than an individual pesticide. And when you do that, the amount of field work and the amount of research seem to be greater. So the absolute number will decline, but we hope they will be more useful documents.

I think the other thing I should say is that we are going to work very hard to make use of the research that has been directed at criteria documents, that in recommendations to OSHA and MSHA, in terms of making it available for worker education, for training professionals, and in that way, try to get more effect out of what had previously been largely in development standards.

Senator SCHWEIKER. Mr. Chairman, Senator Hatfield has a question about an article, in the name of the Center for Disease Control, and I would like to have that answered for the record. And as I also mentioned earlier I have questions on the flu program. I want those to be answered for the record.

Senator MATHIAS. Could I play catchup?

Senator CHILES. Yes, if you give me 1 more minute, I will allow you to take it.

LOW-LEVEL RADIATION

Let me just—what is CDC doing in the effects on workers of exposure to low-level radiation, if you take?

Dr. FOEGE. The Secretary, at the press conference this morning on low-radiation problems, indicated we are doing a number of studies, one in Utah where we'll be signing a contract with the University of Utah to follow up on the child leukemia rates in Utah. We are also completing a study on the bomb blast Smoky, and we are trying to follow 3,213 individuals that we know were at the test site.

We have been successful in getting some records on 85 percent of those people and we have found that while we expect 3.5 cases of leukemia in that group in the last 20 years, that we have found 8 cases which would be about twice the rate. We don't know the real signficance of that.

If many of these people were exposed to two or three or five bombs, they would have had much higher rates of radiation than we expected, or if they were exposed to other agents that we know cause leukemia, that could have been the reason why they had the high rates.

We are also doing a study of Portsmouth Naval Yard where one researcher has found an increase of leukemia among the workers of that naval yard. We are doing a cohort study now on 27,000 workers, and it will take us about 24 months. But we have good exposure data which we will follow up on to determine health outcomes. We will get death certificates for the people that died, we will get medical records for those that have not died to see if we can find a relationship between low-level radiation and health.

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CHILDHOOD IMMUNIZATION INITIATIVE

Senator MATHIAS. As you know, 2 years ago the Center for Disease Control began its childhood immunization initiative to reverse the declining trend of immunization levels among children by the fall of this year.

The Nation, as a whole, has made important progress in this intensive effort.

I am proud to say, Mr. Chairman, that Maryland, and more specifically, Baltimore, have been leaders in this important program.

Their leadership has been crowned with success. Let's look at the numbers—in 1976, the State of Maryland registered 718 cases of measles; in 1977, the number of measles cases was down but still too high at 399 cases.

But last year, as a result of the nationwide effort to immunize more children, Maryland registered only 51 cases of measles.

The results in the city of Baltimore were also impressive. In 1976, Baltimore confirmed 14 cases of measles and 5 cases of rubella, but last year, the comparable figures were 4 measles, 1 rubella.

A major cooperative effort by the Baltimore City Health Department and Baltimore City School System was launched in late 1977 and early 1978 to protect all secondary schoolchildren against the measles.

During this campaign, more than 70 special immunization clinics were conducted. Since which, presumably as a result of, not a single case of measles has been reported among secondary children in our largest city.

A similar effort aimed at protecting Baltimore elementary schoolchildren against all of the childhood diseases began last spring and resulted in 10,000 children receiving needed immunizations by the end of September. I just cite those results and call them to mind because we in Maryland are proud of these results.

Unfortunately, not everyone has made such remarkable progress. Additional funds are needed not only to bring other cities and States up to par with Maryland's program, but also to insure that Maryland's momentum does not lag.

SUPPLEMENTAL REQUEST

I therefore endorse the Center's request for $12 million in fiscal year 1979 supplemental funds to complete the job of improving immunization levels.

Do you think you will have attained your goal of immunizing at least 90 percent of our Nation's children by October 1, 1979?

Dr. FOEGE. Senator, if I can continue your testimonial, indeed Maryland has done an exceptional job and they have shown 99 percent levels of immunization for the vaccines, which I think is incredible.

They also have the distinction of very good cooperation not only between the State, the city, the local health departments but also Johns Hopkins has been involved with this particular program.

Senator MATHIAS. I will see that Mary Shaffer and Dr. Muller receive copies of your comments.

Dr. FOEGE. The $12 million supplemental request is certainly needed to reach the goal by October 1. We believe that we will reach the goal, and in Maryland a very important lesson has been learned; that is, that the schools may turn out to be the strongest single lever that we have in the entire child immunization program. If the schools are willing to enforce school entry laws, then you can get to 99-percent levels. It's where the schools will not cooperate that we have the problem.

About next year, we are in a different situation because by October 1, we should have taken care of the backlog of 20 million children behind in their immunization and at that point, the program will really concentrate on the 3 million new births each year, where we try to have a very tight program on those children. We quite honestly believe we can continue with the same sort of immunization levels, and at the same time, let me alert you to plans that we are developing. Since we made these decisions and we made these requests, it's become clear to us that the program is working so well, that we could try for a new objective; to actually eliminate the transmission of measles in this country as an indigenous disease. We obviously still will have importations and would have to control them but we believe it's possible. It takes a lot of courage to even try for the goal, but we think it's possible to reach the goal. The Secretary has told us to work on a plan, make calculations on what it would cost and he's willing to support our efforts to eliminate measles.

Senator MATHIAS. Our staff here looked at some of the reports that you have made, and I am warning you that we do occasionally read these reports, not always, but occasionally, and we have come up from your own statistics with the fact that of 50 million children in the country that are 14 years old or younger, 52 million, approximately 20 million have not been adequately immunized against childhood diseases.

Now, that's not 10 percent, that is considerably higher, it's closer to 40 percent. About 36 percent are not immunized against polio, and 35 percent against German measles, 30 percent against measles and 24 percent against diphtheria, prostosis, and tetanus.

Now if those are the figures, how can we possibly achieve 90 percent by October 1?

Dr. FOEGE. Two things, the figures were derived from a Census Bureau survey that was done in 1976, and again in 1977, so that the figures are where we stood at the beginning of the program.

We think the figures are now much better than that. Second, they are the result of surveys of parents, asking them by history, "has your child been immunized" rather than looking at a record.

We suspect that the rate of measles may be more sensitive as to what is happening with immunization programs. Last year, we had a 53 percent reduction in measles nationwide.

In the first 7 weeks of this year, 6 of the 7 weeks have set new records for being lower than any previous similar week in the history of the United States; in fact, in Maryland, there was only one case of measles in all of January so we believe from the disease incidence figures that our immunity levels are probably much higher than the Census Bureau survey indication.

Senator MATHIAS. So you don't think the information culled from parents is necessarily the most accurate?

Dr. FOEGE. We are sufficiently concerned that we are now doing a study comparing what a parent says and what the blood test shows in the child, so that we hope by next year, we can make some comparison.

COST-EFFECT STUDY

Senator MATHIAS. Have you done any, what the Corps of Engineers would call a cost-effective study on what a dollar spent today in this program would save in the next 10 years, or 20 years?

Dr. FOEGE. We have indeed done some studies. In fact, earlier I mentioned that fluoridation was the second best benefit/cost program in public health, hoping someone would ask me what is No. 1.

Senator MATHIAS. I now ask you.

Dr. FOEGE. No. 1 one is polio immunization. We figure $90 are saved in health care costs, rehabilitation costs and long-term costs for every prevention dollar invested.

For measles, the figure is about $10 saved for every $1 invested. For rubella and mumps, we do not have nationwide figures but the State of Massachusetts has studied this and reports for both of those that the benefits exceed the cost. Indeed, it's not simply quality of life that is important, there are also financial savings.

Senator MATHIAS. If you have any additional figures in relation to the cost benefit of these expenditures, we will keep the record open for you to add that.

Dr. FOEGE. Thank you.

Senator MATHIAS. Now, I want you to give me an answer, very candid answer, even with these gentlemen sitting here at the end of the table, in your heart, can you assure this committee that what you have requested, or what the President has requested, I don't know what you requested, but what the President has requested, for the fiscal year 1980 will be sufficient and adequate to maintain any percent level of issues, deep, in your heart?

Dr. FOEGE. Given what we know at the moment, we believe this is in fact an accurate and honest request and, because this program is very important to me, I will have no hesitancy to make a request for supplemental funds if we feel we are running behind or having any difficulties.

Senator MATHIAS. Now, we hope that you will be able to get your answers to the questions that have been propounded and any further questions propounded to you in writing and all transcript back to the committee within 7 working days of today. If that would pose any serious problem for you, we'll try to get the transcript to you tomorrow, so you will have adequate time to make those issues.

[The following questions were not asked at the hearing, but were submitted to the Department for response subsequent to the hearing:]

Questions Submitted by Senator Schweiker

LIABILITY

Question: Have you finally resolved the liability issue regarding flu immunizations? What is the status of your work in this area?

Answer: The issue of liability associated with immunization has not been finally resolved. A report summarizing the considerations involved in vaccine liability was submitted to Congress in May 1978. In addition, a contract has been let by the National Center for Health Services Research to develop medical profiles and cost estimates for the most common serious complications of vaccination. A preliminary report from that contract is due on July 1, 1979. It is important to note that all influenza vaccine purchased with influenza grant funds were administered using an HEW special information form which summarized the risks and benefits of vaccination. To date, no claims have been made against the Government related to reaction to vaccine administered this year.

DIMENSIONS OF INFLUENZA PROBLEM

Question: What are the dimensions of the influenza problem in terms of morbidity and mortality?

Answer: Influenza infections occur every year and periodically occur in epidemics in which there is excess mortality as well as a high degree of morbidity. During major influenza epidemics as much as 30 percent of the population may be infected. Excess mortality during influenza epidemics may reach almost 70,000 as indicated in the table below.

ESTIMATED EXCESS MORTALITY
ASSOCIATED WITH INFLUENZA EPIDEMICS
October 1957 - February 1976, U.S.A.

Period of Excess Mortality	Esti. No. of Excess Deaths Due to Pneumonia and Influenza	Estimated Total Excess Deaths	Type of Influenza
Oct. 1957-Mar. 1958	18,500	69,800	A/Japan/57
March-April 1959	1,400	7,900	A/Japan/57
January-March 1960	12,700	38,000	A/Japan/57
January-March 1962	3,500	17,100	B/Maryland/59
February-March 1963	11,500	43,200	A/Japan/62
February-March 1965	2,900	14,900	A/Taiwan/64
February-April 1966	3,700	15,900	A/Taiwan/64
January-February 1968	9,000	23,800	A/Georgia/67
Dec. 1968-Jan. 1969	12,700	33,800	A/Hong Kong/68
January-February 1970	3,500	17,300	A/Hong Kong/68
January-February 1972	5,600	24,600	A/Hong Kong/68
January-February 1973	6,700	24,800	A/England/72
January-February 1976 *	10,002	32,517	A/Victoria/75

* Based on 10% sample of National Center for Health Statistics mortality data.

Question: Does influenza lead to deaths that would not otherwise have occurred and, if so, how many?

Answer: As indicated in the previous answer, significant increases in mortality due to all causes, including causes specifically reported as pneumonia and influenza, frequently occur in association with influenza epidemics.

Question: How did you arrive at the figure of 1800 "Excess" deaths to be averted under your FY 80 immunization plans?

Answer: We cannot predict when the next epidemic will occur and exactly how severe it will be. However, for purposes of estimating the benefits of an annual immunization program directed toward high-risk groups, we have assumed that during a given epidemic there would likely be in the range of 15,000 total excess deaths and that the vaccine would be only 70 percent effective- a very conservative estimate. We further assumed, based on data obtained from the National Center for Health Statistics, that at least 60 percent of these excess deaths will occur in high-risk individuals -9,000 deaths in a population of 42 million high-risk individuals. If we immunize 30 percent of the high-risk population with a vaccine which is 70 percent effective, we should reduce the mortality by 21 percent. This would amount to approximately 1800-1900 excess deaths prevented.

THE FLU PROBLEM THIS YEAR

Question: Have there been any deaths from Russian Influenza this winter? What about other forms of flu?

Answer: Most influenza activity during the 1978-79 influenza season has been associated with "Russian" types H1N1 of influenza. Overall mortality in the United States has not exceeded normally expected levels. However, one child who died with Reye's Syndrome had evidence of infection with the H1N1 influenza virus. Epidemiologic data currently being collected indicate that another 12 deaths may be associated with the H1N1 virus.

Question: Identify the population groups most affected by the current flu "Problem."

Answer: Outbreaks of influenza-like illness this winter have been confined to the under 26 age group, largely to children in elementary and high schools. Only occasional cases in adults have resulted from these outbreaks. For example, during an outbreak investigated in Los Angeles, California, one female, 40-years-old, out of a staff of six at an elementary school, became ill with influenza-like illness during an outbreak at that school. Similar findings have been obtained from investigations in Florida and in other States. Outbreaks among Army personnel have also been confined to the age group 18-24 years of age, with only occasional illness in older individuals.

H1N1 virus has been cultured from adult individuals age 34-86 years, but these have also been isolated cases and have been few in number.

Question: Are these the groups the immunization program had targeted?

Answer: Only to a very limited degree. The Immunization Program focuses on the groups most likely to suffer severe complications or death as a result of influenza infection rather that those most likely to become ill. In virtually every epidemic of influenza, the population groups most affected in terms of illness are youngsters; however, severe complications or death are more frequent in older individuals and in younger people who have medical conditions.

BROADENED "RISK" GROUPS

Question: What age groups do you consider high risk?

Answer: During influenza epidemics, death rates from pneumonia and influenza begin to rise in population groups above age 45 and rise most steeply in those above age 65. In consequence, the age groups traditionally considered high-risk have been those above age 65 although there has frequently been consideration that those from 45 on should be considered high-risk and immunized.

Question: Is the risk of death posed by flu alone high enough to warrant the present Federal program?

Answer: Yes. The calculations of Dr. Joel Kavet and others have indicated that the economic benefits of annual influenza immunization of high-risk groups far outweigh the cost of immunization. Influenza is the only infectious disease which is directly represented in the top 10 causes of death in the United States.

NUMBERS IMMUNIZED

Question: How many people have been immunized under the current Federal flu vaccination program?

Answer: In the period October 1978-January 1979, a total of 986,346 persons have been immunized through the Federally supported influenza immunization program. These data are not final but are quite close to the final totals.

Question: I understand we may be falling short of our goals. If so, why?

Answer: It appears that the Federally supported program will deliver less than one-half of the originally anticipated 3.5 million doses of influenza vaccine during the 1978-79 season. Reasons cited most frequently by the 48 project grantees for the relatively low performance are as follows: Forty-three of the 48 reported that delay in availability of funds and/or vaccine was an important factor, and related to this was a decision not to permit influenza program needs to detract from childhood programs - specifically mentioned by 28. Insufficient public information and education at the National, State and local level was mentioned as a major factor by 29. Local inability to hire personnel, issues of vaccine liability and the complexity of the vaccine recommendations were each mentioned as important factors by 17 grantees.

Question: What rates of immunization are the States reporting?

Answer: Immunization levels are not reported by individual States. National immunization levels will be determined by a survey being carried out under contract to the Opinion Research Coporation in February and March 1979, and from the National U. S. Immunization Survey to be carried out in September 1979. Beginning in fiscal year 1980, data will be available from the National Center for Health Statistics which will provide weekly survey data concerning immunization levels.

Question: Is there a lack of acceptance of the program by the public and the medical community?

Answer: There has been little overt opposition to the program; however, there has not been a great deal of enthusiasm in many circles. An opinion survey is being conducted during February and March of 1979. Results from the survey should be available during early April. A similar survey conducted in 1977 and 1978, indicated that 53 percent of adults in the country would want a flu shot if there was a National program. This compares to 59 percent in 1976, just prior to the Swine flu program when public acceptance of influenza immunization was its highest. Acceptance among the high-risk group is expected to be considerably higher than the general population.

GUILLAIN-BARRÉ SYNDROME

Question: What studies have you done to find out if Guillain-Barrè Syndrome is associated with all types of flu vaccines? Is one needed? Could it be done?

Answer: A special surveillance study is being carried out with approximately 50 percent of all members of the American Academy of Neurology. The study involves monthly contacts with the neurologists to determine how many cases of Guillain-Barrè Syndrome they have seen, and whether or not the individuals have received vaccine. Preliminary data from the current season indicate little or no increase risk of GBS in recipients of the 1978-1979 influenza vaccine.

Question: What would be the cost?

Answer: The cost of this study is $75,000.

BUDGET REQUEST

Question: What is the basis of your request of $15 million for flu immunization programs in FY 80? Isn't this about double or triple the amount provided for the 1978 flu season?

Answer: The original budget estimates called for a grant appropriation of $11.9 million in 1978, $15 million in 1979, and $15 million in 1980. These estimates were based on States and communities being able to provide about one-third of total program costs in 1978 and 1979, and about half the costs in 1980. These estimates also projected that the immunization level of the medically high-risk could be increased from 20 percent in 1977 to 40 percent in 1978 to about 45 percent in 1979, and to about 50 percent in 1980.

Question: Did you spend all the money we gave you last year?

Answer: Because of the delays in obtaining funds in 1978, only $6.4 million in grants was made available in the 1978 supplemental appropriation and only $5.1 million was obligated.

FLU EPIDEMICS OLD AND NEW

Question: Compared to 1918, the year most often cited as an example of the worst that could happen in a flu epidemic, we have many drugs and antibiotics available today to treat flu and its complications. How does the availablility of these therapies alter estimates of potential mortality in an epidemic?

Answer: While it is true that the 1918 epidemic was the worst in the century, we are concerned about more recent experiences. Antibiotics and drugs were available in 1957 during the Asian influenza epidemic; nonetheless, an estimated 70,000 persons in excess of the expected died as a result of influenza infection. During the 1968-69 Hong Kong influenza epidemic, the excess mortality was approximately 33,000, also in spite of the availability of drugs and antibiotics. The availability of antibiotics and drugs clearly makes it possible for us to treat many of the bacterial complications of influenza but deaths related to flu continue to occur.

Amantadine is the only drug licensed for the prevention and symptomatic treatment of influenza itself. The potential of this drug for reducing mortality is not known. Studies are being conducted on other unlicensed drugs which may be used to prevent or treat influenza in the future.

NEXT WINTER'S THREAT

Question: What do you foresee for the next flu season? Are you projecting a serious outbreak?

Answer: We cannot predict with certainty what kind of influenza activity there will be during the 1979-80 flu season. Vaccine formulation will be based on our best estimate which is based on the occurrence of influenza throughout the world this winter. To date, we have seen concurrent circulation of influenza B and two types of influenza A--H3N2 (A/Texas) and H1N1 (predominately A/Russia and A/Brazil).

Question: Are there enough uncertainties about this to warrant holding off with another flu program?

Answer: It is precisely because of the uncertainties regarding annual influenza activity that advisory groups have felt annual influenza immunization is essential. Our previous experiences indicated that we have not been able to produce vaccine and administer it in as short a time as would be required if we waited to see how much influenza activity was actually occurring in a given year. Production of influenza vaccine and preparation for its administration must begin many months before the influenza season. Moreover, it is recommended that vaccinations be given before the transmission season begins, as protective antibodies

require 2 to 4 weeks to develop and influenza can spread very rapidly.

Thus, decisions about vaccine formulation and production will be made soon, irrespective of a decision about Federal support of public programs. We feel that this latter decision must also be made soon in order to insure adequate production of vaccine for public programs and to establish an effective administrative capability in the States.

Question: What progress are you making in developing vaccine recommendations for the coming year?

Answer: At the Surgeon General's Conference on Influenza on February 12, recommendations were made as to the composition of vaccine and on the population groups to be vaccinated. The following summarizes the conclusions and recommendations of the Surgeon General's meeting on influenza:

1. Currently two subtypes of influenza A virus are causing human illness, H1N1 and H3N2. H3N2 viruses first appeared in this century in 1968 and have been prevalent ever since. Successive mutations have caused antigenic drift, with A/Texas/77 strain being the contemporary H3N2 variant. No isolations of H3N2 viruses have been made this season in the United States, but they have been reported from other parts of the world, and it must be presumed that these viruses could recur in epidemic form. Two years ago, H1N1 virus, which was prevalent from 1947 to 1957, reappeared as the "Russian" strain. The A/Brazil/78 strain, the most common H1N1 virus encountered recently, has been shown to be modestly different in antigenic composition from its predecessor, A/USSR/77. Although simultaneous occurrence of two major subtypes is unusual, this occurred in 1977-1978 with H1N1 and H3N2 and it is currently happening in some countries. Thus, the replacement of one subtype by the other cannot surely be predicted. Influenza B viruses continue to cause illnesses. Recent isolates have been relatively unchanged from the B/Hong Kong prototype. Therefore, for 1979-1980 a vaccine to protect against epidemic influenza should contain influenza B and both H1N1 and H3N2 variants of influenza A.

For a number of years efforts have been made to use the most recent viral strains in the manufacture of vaccine. Although A/Brazil/78 and A/USSR/77 are distinct antigenic variants of H1N1 influenza virus, they are sufficiently similar that A/USSR/77 could be substituted for A/Brazil/78, if production difficulties arise with A/Brazil/78. Some participants also felt that existing stocks of influenza vaccines containing A/USSR/77 (1978-1979 formulation) could be used in the coming season up to their expiration dates. If these vaccines are used, the dosage schedules given in the package insert should be followed. Other participants felt that the 1979-1980 vaccine should contain A/Brazil/78, the H1N1 strain recently causing epidemics in the United States. In addition to being the most contemporary vaccine formulation possible, this would avoid potential confusion resulting from the distribution and use of several vaccines, and it would simplify the explanation of recommendations to physicians and the public.

2. Vulnerability to influenza infection and response to vaccine are, in part, functions of prior experience with the various prevalent strains of virus. Most people over 26 years of age were infected with H1N1 viruses during the 1947-1957 period. During the past 2 years a significant proportion of the population (of all ages) has been either reexposed or newly exposed to H1N1 viruses. Response to H1N1 virus in vaccine has been excellent in people over 26, but younger people not previously exposed have required two doses for an adequate antibody response. Most of the United States population has been infected with H3N2 virus in the past 11 years (as well as influenza B virus) and thus respond well to a single dose of vaccine containing these antigens.

3. Influenza A epidemics are regularly associated with excess mortality. Approximately half of the excess deaths are ascribed to cardiovascular disease, and a third are attributed to influenza and pneumonia. The risk of death among persons infected with influenza virus increases sharply with age among adults over 45 years. The greatest lethality occurs in people with chronic cardiac or pulmonary disease, and their risk is high at any age. Since the rise in mortality with advancing age cannot be apportioned with certainty among those with and without chronic illness, the prudent course is to offer protection to all persons above some stated age, while understanding that the risk increases continuously as age increases. Age is a significant risk factor independent of underlying chronic illness.

4. Intensive evaluation of the safety and potency of whole and split influenza virus vaccines reveals that antibody response is very good after one dose in persons previously primed, and two doses produce a satisfactory response in unprimed individuals. Standardization of dosage is now done by measuring amounts of hemagglutinin antigen present in the vaccine. In the doses recommended, immediate reactions to the vaccine are mild and occur at frequencies so low that they are not significantly different from placebo. Occurrence of Guillain-Barrè syndrome (GBS), the serious late complication that was observed in association with A.New Jersey influenza vaccine in 1976, has been monitored carefully since January 1978. Only eight cases occurring within 8 weeks of influenza vaccination in 1978 were reported, and these did not cluster within the eight-week period. This study is not complete, but the data now available suggest that the risk of GBS is not significantly elevated among recipients of vaccine in 1978.

5. Amantadine, licensed for use against influenza A viruses, was shown to be beneficial both in the prophylaxis and treatment of illness caused by influenza A/USSR/77 viruses during studies conducted in 1978. This drug reduced the incidence of illness by approximately 60-70%, and it reduced the duration and intensity of illness and viral shedding when used for the treatment of patients with influenza. Side effects were mild and infrequent and observed primarily within the first 2 days of drug use. Side effects were limited to central nervous system symptoms, e.g., occasional insomnia or nervousness. Rimantadine was also found to ameliorate influenza illness when used for treatment; side effects were less frequent than observed with amantadine. Rimantadine is not licensed in the United States.

In response to the specific questions raised by the Surgeon General in his introduction and meeting objectives, the meeting recommends the following:

1. COMPOSITION OF VACCINE FOR THE 1979-1980 Influenza Season.

For 1979-1980 the vaccine should contain 7 micrograms of hemagglutinin antigen representative of each of three influenza viruses - B/Hong Kong/5/72, A/Brazil/78 (H1N1), and A/Texas/77 (H3N2) - in each 0.5 ml dose.

2. DOSAGE SCHEDULE FOR VACCINE USE.

Age Group	Product	Dosage Schedule
27 years & older	whole or split virus	0.5 ml
13 - 26 years	whole or split virus	0.5 ml x 2 doses
3 - 12 years	split virus	0.5 ml x 2 doses
6 - 35 months	split virus	0.25 ml x 2 doses

This schedule is simpler than last year's; only one concentration is recommended, and the dose is standardized except for the half dose for infants and small children. Split virus vaccine is recommended for those under 13 to assure that the frequency of immediate vaccine reactions is kept as low as possible.

Any person who received influenza vaccine during the 1978-1979 season needs to receive only one dose of vaccine this year, regardless of age.

3. NEED, IF ANY, FOR CLINICAL FIELD TRIALS WITH THE VACCINE.

Although a number of studies of the vaccine will be conducted this year, no special studies were judged necessary to formulate proper recommendations for vaccine use.

4. DELINEATION OF THE TARGET GROUPS TO RECEIVE VACCINE.

Annual vaccination is strongly recommended for people of all ages who are at increased risk of adverse consequences from infections of the lower respiratory tract. Conditions predisposing to such risk have been outlined in 1978-1979 ACIP recommendations.

The risk of death associated with influenza increases sharply with age, so that from age 65 upward, age becomes an increasingly important justification for immunization.

Questions Submitted by Senator Mathias

SWINE FLU CLAIMS

Question: What is the status of the damage claims from the swine flu immunization program?

Answer: As of February 9, 1979, a total of 3,600 administrative claims amounting to $3,319,080,967.89 had been filed against the United States. Of this total 1,037 claimants alleged Guillain-Barrè as the injury with a total of $947,319,625.51.

As of February 16, 1979, a total of 443 claims amounting to $171,828,253.10 had been administratively denied; and, a total of 14 claims amounting to $72,533.15 had been settled. Of these, 5 alleged Guillain-Barrè as the injury with a total amount of $27,386.75.

Question: Can you show a direct correlation between your venereal disease education and treatment programs and the incidence of venereal disease and those areas which do not have such programs?

Answer: Since all State and local VD control programs includes education and treatment components, we cannot make the comparison you request. All control program components (screening, epidemiologic services, treatment, education, and laboratory and diagnostic services) function together to affect disease incidence in any given program area. The major contribution of Federal funding has been the implementation of consistent programs throughout the country so that all areas have these basic program components. There has been a clear correlation between the level of Federal funding and trends in venereal disease control.

STATE LABORATORIES

Question: What kind of progress have you made in the past five years in improving State laboratories and also in reviewing and monitoring private labs across the United States as well?

Answer: Major efforts carried out by the Center to improve the State laboratories and front line clinical and hospital laboratories have been through technology transfer by training and consultation; through a small but sharply focused program of financial assistance to public and private organizations for the conduct of intrastate or multistate regional laboratory improvement programs; and through the regulatory program set forth in the Clinical Laboratories Improvement Act of 1967 (CLIA 67).

From its inception the licensure program has emphasized improvement of laboratories rather than regulation per se. On-site examinations and critiques based on proficiency testing data are used as valuable educational tools and as a framework around which laboratory improvement efforts may be implemented and their effects assessed. One clear example of the improvement in laboratories is the decrease in the number of deficiencies uncovered in the examination process. For a first examination, the average number

of deficiencies per laboratory was 22. In the second examination, 15 were noted for a reduction of 34% and in the third examination, 10 were noted for a reduction of 37%. During the past five years, approximately 3,598 on-site quality control examinations of clinical laboratories have been performed by CDC. In addition, the number of laboratories participating in the CDC proficiency testing program have increased from 1,500 to 2,600.

Productivity of the laboratory training activity has been raised 25% in terms of courses produced and students trained since 1975 with the same size staff. CDC has addressed the problem of under-trained rural laboratory workers by assisting States to organize telephone teaching networks aimed at rural hospitals. The gains in laboratory improvement through training which have been made in the past five years have been significant in terms of numbers but perhaps the most significant gain has been made in identification of specific laboratory problems and special needs and the focusing of programs designed specifically to correct them.

A third effort, laboratory improvement contracts, was begun in FY 1977 when CDC negotiated 16 contracts in the areas of laboratory training, proficiency testing, technical consultation, and on-site inspection within 10 States. A total of 22 new contracts were awarded in FY 1978 to 16 States in the same areas except on-site inspection and approximately 22 more are expected to be awarded for this year. Approximately 6,791 laboratories have participated in the various programs covered under these contracts.

Question: How far do we yet have to go in this area?

Answer: Recognizing that CDC's efforts can have only limited impact on the enormity of the national training deficit, much emphasis needs to be placed on providing technical assistance to States as an aid in increasing their capacity for providing training on an intra-state basis. Diverse training providers including universities, professional groups, and government agencies need to be coordinated to develop a unified program.

Efforts to continue to improve laboratory results will be enhanced through inclusion of more laboratories in proficiency testing and on-site inspection programs. The CDC must emphasize the development and improvement of laboratory technology in analytical methods, high quality calibration and control materials, and procedures for quality assessment and control. We must continue to assist and cooperate with State agencies and private associations in achieving the broadest possible acceptance and application of high, uniform standards of laboratory practice which are designed to assure accurate and reproducible diagnostic laboratory test results.

The establishment of active laboratory improvement programs at the State level would contribute greatly to progress in this area. The developmental assistance contract program has produced model programs that States could implement.

HEALTH EDUCATION

Question: As you well know, the Committee has a strong interest in the area of Health Education and has been encouraging new and young program directors to be much more active in this area.

What programs are you particularly pleased with in this area?

Answer: (1) In school health education, the development and spread of basic school health curricula for grades K through 7, which have been enthusiastically received by pupils, teachers and parents in more than 35 States. Also, the vigorous support of the National Congress of Parents and Teachers and its State and local affiliates in stimulating greater attention to the need for better health education in schools across the country.

(2) In patient education, the culmination of a four-year project with the American Hospital Association which has produced, for the first time, an assessment and reassessment of the number of active patient education programs in hospitals; the development of model programs for patient education in such subjects as diabetes, chronic lung disease, medication teaching, use of media in patient education, etc.; and during the current year the conduct of workshops for clinicians and educators to improve methods and outcomes of patient education programs.

(3) In community health education, a highly productive collaboration with the Cooperative Agricultural Extension Service in Arkansas in using that excellent rural outreach system as a channel for health education; a project in New Mexico testing health education methods for rural and Urban American Indians and Mexican-Americans; a project in Alabama to develop very basic health education methods for rural blacks.

(4) Scientific study of evaluation methods in health education, with particular emphasis on diabetes education, sex education, and attitudes and practices related to immunization.

Question: What has been accomplished in fiscal 1979?

Answer: FY 1979 has witnessed the culmination and dissemination of results of the projects just described. In addition, several major initiatives are now getting underway:

(1) A grant program to create in official health agencies at the State level a center of expertise and coordinating force for programs aimed at personal choice health behaviors having an influence on health, including but not limited to smoking, diet, alcohol and

substance abuse, exercise, and other behaviors which lend themselves to risk reduction through lifestyle change.

(2) A series of demonstrations of effective sex education programs for young people, primarily aged 10-15, under a variety of auspices (schools, youth groups, parent organizations, etc.) based upon a study done in FY 1978 to determine measurable outcomes of sex education activities in programs considered successful.

(3) Continuation of work underway in 1978 to establish a private-sector based center of expertise for school health education through a contract with the National Center for Health Education, which will assume increasing responsibility for the development, refinement and diffusion of effective school health curricula.

(4) Initiation of projects to develop health education modules for use in schools at the junior and senior high school levels, to complement work already done for elementary schools.

(5) Testing of the effectiveness of health risk appraisal techniques in various settings as a means of motivating lifestyle change by individuals.

Question: What new emphasis and program areas do you plan for for fiscal 1980?

Answer: FY 1980 will witness strengthening and augmentation of the grants program to States initiated in 1979, with specific additional support being given to those States which demonstrate commitment and propose innovative projects in the area of personal choice health behavior (lifestyle) education programs. We will also evaluate, and modify as necessary, the sex education activities initiated in 1979.

FY 1980 plans include a major evaluation project, to be conducted jointly with the Office of Health Information and Health Promotion, of the effectiveness of a variety of school health education curricula now in use in various school systems around the country, to determine their respective impact on knowledge, attitudes and behavior of young people and their effect on the school and community systems where they are being used. This large-scale evaluation will be based in part on a study now underway in FY 1979 of appropriate measures that can be applied to school health education. In FY 1980 special emphasis will be given to health education at the worksite, applying and making available to public agencies and private enterprises the results of pilot work now being done on employee health education using risk appraisal approaches.

Also in 1980, based on work being initiated in 1979, we intend to stimulate more effective health education programs conducted in outpatient settings (HMOs, group practices, clinics, etc.) to parallel the activities already carried out in hospital settings.

Question: How does your health education program tie in with the health education programs in the Office of the Assistant Secretary for Health?

Answer: CDC's basic role in health education is that of an operating program, supporting through grants and contracts and through technical assistance the development and spread of improved health education methods, the evaluation of health education programs, and strengthening the capabilities of public and private sector organizations to carry out better health education activities. This role is complementary with the functions of the OHIHP and the newly-created Office on Smoking and Health, which serve as staff offices for policy/development, spokesmanship, and active program coordination among the many HEW components engaged in health promotion and education. Specific examples of collaboration now underway include:

(1) With OHIHP, joint support and management of school health evaluation;

(2) CDC participation in Regional Forums, Community Technical Assistance and other initiatives of OHIHP;

(3) Close dovetailing of CDC's data collection in health education methodology with OHIHP's broader responsibility for developing a national clearinghouse for health information;

(4) Exchange comment and joint review of major projects among the three organizations, including grant guidelines, contract RFPs, and the like.

Question: Give us some specific examples of how your health education programs have coordinated and initiated projects with the Office of Education and the Nutrition Education program in USDA?

Answer: (1) CDC and the Office of Education jointly supported the initiation of the project with the National Congress of Parents and Teachers already alluded to, and OE has continued to provide input to this activity although CDC has borne the full financial support since the first year.

(2) CDC is currently working with the OE to accomplish the validation process which will enable the School Health Curriculum Project supported by CDC to become a part of the OE Diffusion System which will encourage its much wider adoption. This will be the first health education curriculum of any kind that has been entered into the OE validation and diffusion network.

(3) The project with the Cooperative Extension Service in Arkansas previously mentioned has contained a substantial nutrition component. Based in part on the success of this activity, CDC is participating in a Task Force reporting to USDA's Extension Committee on Policy which has drafted a Memorandum of Understanding for

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signature by high officals in both Departments to assure continuing collaboration and mutual support of health education activity. Plans are now underway for CDC to initiate such joint support with USDA in FY 1979.

(4) In FY 1979, CDC is supporting a contract, in close cooperation with the Administration on Aging, to train older persons to act as nutrition educators for their peers. The project will involve preparing and testing training courses, and using them in selected sites to test the validity of the method.

EXPOSURE TO LOW LEVEL RADIATION

Question: Dr. Foege, we are hearing more and more about the possible health effects on workers from exposure to low-level radiation, like with the leukemia rate in Utah.

What is CDC doing in this area?

Answer: CDC has become increasingly involved with epidemiologic evaluations of the long-term health effects of exposure to low levels of ionizing radiation during the past two years. Our major efforts include:

(1) A study of participants at the nuclear test Smoky. Results so far suggest an increased incidence of leukemia among this group of soldiers. A larger study of participants at other bomb blasts is being prepared by other agencies (NAS, DOD, DOE) and CDC has provided some consultation based on the Smoky experience.

(2) Participation in the Interagency Task Force on Radiation whose report was released to the public last week. CDC personnel chaired the subgroups which reviewed the known scientific data and made recommendations about prevention of radiation exposure.

(3) A study being conducted by the Center's National Institute for Occupational Safety and Health of the long-term health effects at the Portsmouth Naval Shipyard where workers who overhaul nuclear submarines are exposed to low levels of ionizing radiation.

(4) We have recently negotiated a contract with the University of Utah to support further epidemiologic studies of leukemia and cancer rates in Utah and to develop more detailed analyses of nuclear fallout patterns in Utah.

Question: How are you coordinating your efforts with the National Institutes of Health?

Answer: Dr. Fredrickson, Director of the National Institutes of Health, is chairing a newly created interagency committee to review the status and needs of research in the area of low-level ionizing radiation. CDC is represented on this committee and will

closely coordinate its research efforts with the NIH and other agencies represented.

We have worked closely with Dr. Upton, Director of the National Cancer Institute, and NCI scientists on the Interagency Task Force on Radiation, and have consulted informally on numerous occasions with regard to the CDC radiation studies outlined previously.

DENTAL HEALTH PROGRAM

Question: As you know, last year Senator Magnuson provided an increase of a little over $1 million to establish and expand the fluoridation program across this country.

What have you done with this funding and what is your budget proposal in this area for fiscal year 1980?

Answer: The increase of $1,189,000 to expand the fluoridation program in 1979 will be used generally to staff the expanded program and to prepare for full scale operations in 1980. In 1979 about $500,000 will be used for the establishment, installation, support, and maintenance of 45 community fluoridation systems and 60 school fluoridation systems. We anticipate that of the 45 systems the estimated population served will be 400,000.

The President has requested an increase in 1980 of $4.711 million which would bring the total for the fluoridation effort to $6.224 million. With this amount, we plan to assist States with equipment costs, installation and start-up costs, operating and surveillance support, and training support for State and local water works personnel. We estimate that an additional 2.6 million persons will be served by fluoridated systems by the end of 1980. It is also apparent that the quality of fluoridation where equipment now exists throughout the country is not always optimum. The assistance to States will upgrade the quality of the existing systems to insure optimum fluoridation, as well as to extend the benefits of optimally fluoridated water to 2.6 million additional people.

Question: We found last year that for every dollar we put into the fluoridation projects across the country, we saved approximately $36.00 in child health dental care.

Is it possible that this figure is correct?

Answer: We are confident that the $36 yield for each dollar spent in community water fluoridation is a conservative figure. Since that estimate was made several years ago, the treatment costs for dental care have markedly increased beyond the costs of providing fluoridated water.

FUTURE PRIORITIES

Question: At the time of last year's hearings, Dr. Foege, you were about to have a meeting with 16 non-Center for Disease Control people from the Public Health community who were to review all your operations and make suggestions on future priorities.

Can you share with us the highlights of their report and what you have done to implement them?

Answer: In July 1977, we initiated a project to plan how CDC can best work toward achievement of its objective: preventing or reducing unnecessary morbidity and/or mortality in the U.S.

The first phase of the project was an extensive mail solicitation of recommendations on what CDC's activities should be to maximize achievement of its objective. Several hundred individuals and organizations representing a wide range of public health interests responded.

The second phase of this project was the specification of recommendations on CDC's future programs and policies by an advisory group composed of prominent individuals in public health from outside CDC. This committee, chartered on December 19, 1977, was designated "The Center for Disease Control Programs and Policies Advisory Committee *Ad Hoc*." Their deliberations were based on the responses to the solicitation, current morbidity and mortality data, and their own experience, insight, and expertise in public health.

Of special interest is the list, developed by the committee, of preventable health problems of high priority:

1. Cardiovascular disease
2. Unsafe food and drinking water
3. Dental diseases
4. Nosocomial infections
5. Smoking
6. Morbidity and mortality caused by hazards in the workplace
7. Vaccine preventable diseases
8. Alcohol
9. Cancer
10. Infant mortality
11. Unwanted pregnancies
12. Morbidity and mortality due to environmental hazards amenable to prevention

13. Preventable infections of Public Health significance and newly recognized diseases

14. Homicide, suicide, assault, rape, child and spouse abuse

15. Motor vehicles and other accidents

After receiving the committee's report, we took the following steps:

1. CDC Staff Conferences were held in September and November 1978 to review the list of priority problems and discuss strategies of intervention.

2. The list of high priority problems was utilized by CDC in the FY 1980 ZBB process and is continuing to influence our on-going program planning, budgeting, and evaluation efforts.

3. In accordance with the recommendations, CDC has attempted to:

   - Strengthen its international health activities.
   - Emphasize relationships with schools of medicine and schools of public health regarding prevention.
   - Strengthen NIOSH's service role in prevention of disease and death in the workplace.

FORMULA GRANTS

Question: For the first time you are requesting $18 million for Fiscal Year 1980 for the Prevention Formual Grant Program. We created the Prevention Formula Grant Program last year, because we believed that States have the capacity to take the lead role in this area if we give them flexibility. However, we do have to know what their activities add up to on a nationwide basis.

What are you doing to monitor how they use this money?

Answer: The States maintain a National Public Health Program Reporting System, which P.L. 95-626 recognized and authorized funding for under Section 314(d).

This system is being strengthened to describe the use of State, Federal, and local funds for prevention and public health. In addition, plans developed under the first year of Section 315 funds, and the specific, measurable objectives required under the law to be submitted as part of the application, will provide excellent information for monitoring State prevention programs.

Question: What can you tell us about how they are planning to use the funds?

Answer: We have met with State people on several occasions. We are in agreement on the basic purpose of these monies, to stimulate additional prevention activity, with the first year devoted, as specified in the Act, to planning for preventive health services,

identifying measurable objectives, and ways to increase State impact on reducing the leading causes of death and illness. Some States will concentrate on a single prevention priority: e.g., cancer deaths. Others will take an integrated approach to a series of related priorities--e.g., risk factors and causative conditions for heart disease deaths, cardiovascular disease.

Question: This is another new program and with this in mind, what are you doing to ensure that the States will use these funds to promote programs in the area of preventive medicine?

Answer: The key features of this new authority are detailed planning, measurable objectives for reducing the causative conditions and risk factors associated with the five leading causes of death and the burden of illness of the five leading causes of morbidity, and the definable commitment of resources to health communications. The results of State planning for prevention, and the detailed plans and commitments required by the Act as part of State applications for grants, will make operational the clear intent to enhance State prevention activities verbally stated in meetings with State Health Agency leaders.

Question: What type of program would you envision individual States initiating with such funds?

Answer: We expect and hope a rich variety of approaches will be developed over the life of this authority. Public Law 95-625 creates a series of prevention authorities which have certain linkages and comments. All support public health and prevention, some in generic ways and some with very specific targets. Section 315 should be viewed in the context of an overall State program specifically devoted in the first year primarily to defining targets for high priority prevention activities and planning new approaches, demonstrations, etc., with linkages to existing State capacity and programs, and to the other prevention authorities in P.L. 95-625. Future years would see implementation of this program, with a special focus on health communications.

REGULATIONS

Question: Give us your specific plans for implementing the new Formula Grant Prevention Program.

Are the regulations written yet? If not, when will they be done?

Answer: We plan to issue proposed regulations for the "planning phase" in the next five months. The NPRM will give notice that additional regulations will be issued in FY 1981 for implementing the programs developed in the first year. The application requirements in Section 315 change significantly between 1980 and 1981. Draft regulations will be completed in the next few weeks, with the expected approval of the Regulations Development Plan we have submitted to HEW's Regulations Development Review Board.

NO POSITIONS

Question: You are requesting the initiation of a new program within CDC and are requesting that no new positions be provided to handle this program.

Please describe for the Committee who and what numbers of people and where they will come from to administer this program.

Answer: A combination of existing staff reassigned to this program and assistance from a variety of CDC technical experts in prevention at appropriate points, will be used to implement the program.

LOW REQUEST

Question: $18 million for the Prevention Formula Grant Program once it is divided among 50 different States must certainly not be much for each State or Region.

What can you expect to accomplish for that amount of money?

Answer: The Act authorizes $20 million. Our request for $18 million is an amount which provides the States an adequate base to meet the Act's intent that States plan and develop innovative approaches, emphasizing measurable targets and health communications. In subsequent years, when authorization is to $60 million and $75 million respectively, the quality of the opportunities available for prevention impact will need to be considered in allocating resources to prevention.

Question: Would we be better off not spending it?

Answer: This program is definitely worth initiating in a phased manner. A year for planning will better assure the implementation of effective prevention programs in 1981 and beyond.

Question: Will most of this funding be used for administrative and salary costs within the various States?

Answer: The funds will be made available to the States on a formula basis to develop a program for primary and secondary preventive services to reduce mortality for one or more of the five leading causes of death in the State.

Question: What has happened to all of those people who suffered Guillain-Barrè Syndrome as the result of the swine flu fiasco? Have you kept track of them?

Answer: We have not kept track of all the Guillain-Barrè Syndrome cases which may have been associated with the swine flu program. There is no specific treatment for patients with Guillain-Barrè Syndrome and the majority, about 80 percent, of patients clinically recover usually within a few months, although improvement may take 1 to 2 years for some. About 6 percent of the cases are fatal and about 5-10 percent of cases do not recover completely.

PUBLICATIONS RELATED TO THE ABORTION ISSUE

Question: It has come to the attention of Members of this Committee that the Center for Disease Control reprinted an article written by an employee of the Center entitled "Abortion, the Bible

and the Christian Physician." The involvement of the Center in the publication of such an article has serious First Amendment implications and it compromises the neutrality of the federal bureaucracy on the difficult issue of abortion. The problems resulting from this particular incident have been resolved.

However, what steps are being taken to ensure that the Center for Disease Control remains neutral in all its actions and publications related to the abortion issue?

Answer: Our role at CDC is to develop factual, objective data on morbidity and mortality associated with abortion and to distribute this information. While individuals at CDC are entitled to their opinions and are free to publish them in the literature, CDC as an institution must have an unbiased approach. In mid 1978, I assured opponents of abortion that I would personally review abortion surveillance issues prior to their release and that I would assume personal responsibility for any biased interpretation. At that time, I also urged opponents of abortion to contact me directly if they felt that any misinterpretations of fact appeared in any of the Center's publications. I have also directed a reevaluation of our internal procedures to assure that appropriate disclaimers are used on CDC reprints. I believe these steps will assure that the Center remains neutral on this issue.

VD INFORMATION AND EDUCATION

Question: The new Venereal Disease Amendments of 1978 require that 5% of all funds appropriated be allocated to programs of information and education. What programs will be established?

Answer: Information and education programs will be established to focus on the development and evaluation of effective educational methods to reach the priority target groups of patients, providers of health services, persons at high risk and the general public, particularly young people. Because of their increasing significance, research and demonstration programs will focus on control methods for sexually transmitted diseases including the development for diagnostic, therapeutic and case-management services.

Question: Will this new 5% requirement jeopardize any existing services?

Answer: At the current level of grant appropriations, we do not expect the use of 5 percent of funds for research, demonstrations, and public information and education to detract from ongoing control efforts.

NUTRITION INTELLIGENCE SYSTEM

Question: A GAO report dated November 7, 1978 was very critical of HEW efforts in the area of Nutrition Intelligence and Surveillance and I quote, "Weaknesses in existing activities include data which is often untimely, not sufficiently specific geographically, omits important population groups, and is inadequate for evaluating program effectiveness."

How would you react to this, Dr. Foege? And given the increased emphasis which the Committee placed on nutrition programs last year, what are you doing to improve this?

Answer: We agree in substance with these observations mentioned in the GAO Report. The Center for Disease Control (CDC) is expanding the surveillance system to include more States and within the participating States additional service programs which will provide surveillance data on other population groups. I believe the National Center for Health Statistics (NCHS) is also taking steps to make their HANES information more timely. The CDC is also working with States to improve the use of surveillance data for selected elements of program evaluation.

Question: What are you doing along with other Public Health Service agencies to create a coordinated national nutrition intelligence system?

Answer: CDC with other HEW agencies participated in the development of the HEW/USDA proposal for a Comprehensive Nutritional Status Monitoring System prepared for the Congress in the Spring of 1978. This proposal is designed to bring together in a coordinated way the various surveillance and survey activities conducted throughout both departments. Implementation of the proposal is underway. The Center has developed in conjunction with NCHS new growth charts which are being widely used in the United States and throughout the world.

Question: What other Federal departments are you working with?

Answer: CDC is working with all PHS agencies, the Health Care Financing Administration and the Administration for Children, Youth and Families. We are also working with the Supplemental Food Programs of the Department of Agriculture and the Department of State in carrying out nutritional surveys in some developing countries.

DIABETES CONTROL

Question: The Center for Disease Control plays an important role in the comprehensive Diabetes Initiative program.

What have you done in the past year relating to this?

Answer: Interventions to resolve identified problems were initiated in six (6) of the CDC's Diabetes Control Demonstration Project States and intervention planning continued in four (4) others. In addition to activity in the project States, CDC's Diabetes Control Activity provided on site technical assistance to 15 non-contract States. At the national level, the CDC NIH-ADA Diabetes Screening Workshop was held to assess the effectiveness of screening programs in the community control of diabetes; as the result of this workshop, appropriate objectives and target groups for such programs were recommended.

Question: And how does your budget request reflect priorities in the area of diabetes for fiscal year 1980?

Answer: The CDC has many competing programs but sufficient resources have been requested for FY 1980 with which to sustain the core capacities (planning, evaluation, surveillance, epidemiology and coordination functions) of 12 demonstration project States. Corrective interventions such as patient and professional education will require a long-term commitment from non-Federal funding sources.

URBAN RAT CONTROL

Question: How many communities in the U.S. have serious rat infestations and can benefit from the funding from the Rat Control Program?

Answer: It has been estimated that 270 cities in this country presently have significant rat infestation problems. There are a number of variables which influence the program's benefits such as local commitment to the program, availability of resources, and continuing deterioration of environmental conditions, particularly in inner cities. Most of these communities could undoubtedly benefit from an Urban Rat Control Project grant if these issues are addressed.

Question: How many cities will, in fact, be able to receive funding due to budget constraints?

Answer: Sixty-eight communities should receive urban rat control grant funds in fiscal year 1980.

Question: How many communities that have received Federal funding for rat control activities in the past are now self-sufficient?

Answer: Twenty-six communities have developed local capacity to address rat infestations in previously funded target areas and are now self-sufficient. Additionally, twenty cities continue to receive grant funds to service new target areas after having assumed total responsibility for maintaining rat control in target areas previously funded by CDC.

Question: There has been a great deal of publicity lately about the so-called "Super Rat". Will you explain what is being done in this area in terms of finding better control mechanisms or poisons?

Answer: The term "Super Rat" is a misnomer used to identify rats with genetic traits making them resistant to the commonly used anticoagulant poisons. A small percentage of these rats are found in all rat populations. Anticoagulants, because of the high safety factor, have been used extensively and indiscriminately in many communities, resulting in an increasing proportion of the rat population demonstrating resistance. Effective alternative poisons are available to meet this problem.

However, it is known that a long term solution to urban rat infestations cannot be achieved through use of poisons exclusively. Rat control methodology must include environmental modification activities to eliminate those conditions conducive to rat proliferation. When these environmental activities are coupled with the appropriate use of effective poisons, the rat infestations can be elininated.

HUNTINGTON'S DISEASE COMMISSION

Question: What is the Center for Disease Control doing in '79 -- and what is its plans in 1980 -- to implement the various recommendations that the Huntington's Disease Commission has made that relate to CDC?

Answer: CDC has a continuing interest in genetic disease, and is currently involved with HSA in the implementation of the new Genetic Disease legislation with respect to Section 1107. This new section of Part A of Title XI was included in P.L. 95-626, The Health Services and Centers Amendments of 1978, which also amended the original genetic disease legislation to broaden the focus of the legislation from nine named disease entities to a variety of conditions of genetic origin, in which list Huntington's chorea was specifically included. (Grant programs authorized by this legislation are administered by the Health Services Administration.) Sec. 1107 authorizes the Secretary to carry out, within an identifiable administrative unit, epidemiologic assessments and surveillance of genetic diseases, and development of control programs that States may implement. Little activity with respect to Huntington's Disease is taking place in CDC.

During 1978, CDC and the National Institute of Neurologic and Communicative Disorders and Stroke (NINCDS) collaborated on a proposal to channel services to HD patients through the Nation's public health system, as part of Departmental consideration of long-term care options. This proposal was based on the CDC Health Services Coordination and Development proposal endorsed by the National Commission on control of HD and its consequences (Commission Report, Vol. I, p. xxvii). The CDC budget for FY 1980 does not include funds for this proposal.

LABORATORY IMPROVEMENT

Question: You are requesting an increase of $762,000 for a 1979 supplemental pay increase which will take the Laboratory Improvement Program to a level of $19 million. Then, the 1980 budget proposes we reduce the program to $18 million.

Why, Dr. Foege, in light of budget restraints and the fact that you intend to reduce the program again in 1980, should we not disallow the pay increase supplemental and have you, in effect, take it out of existing programs?

Answer: There are two aspects to the laboratory improvement at the Center. We have our basic activities which are devoted to upgrading the Nation's clinical and public health laboratories. This program monitors the effectiveness of the application of standards to laboratories under the purview of the Federal Government and cooperates with State agencies and private associations in achieving the broadest possible acceptance and application of high, uniform standards which are designed to assure accurate and reproducible diagnostic laboratory test results. We train State and local laboratory workers; conduct proficiency testing programs; produce standard reagents; and test commercial laboratory products.

The increase in this activity is for pay cost. It is necessary to continue efforts to improve the Nation's clinical and public health laboratories. More efficient and innovative methods have permitted us to overcome the cost of living increases in laboratory materials and supplies, but, it is necessary to have increased funds for the pay raise without reducing our efforts.

Supplementing the basic activities is a program of developmental assistance in the form of contract monies to upgrade intrastate laboratory improvement programs. In 1979, 25 contracts were awarded in three areas: laboratory training, technical consultation, and proficiency testing. To date, over 3,000 laboratories and 10,000 health laboratory workers have been affected through these contracts. The program decrease of $1,987,000 results from the termination of this contract program and does not reduce pay requirements for the basic program. The States which have received contracts will serve as models for future improvement efforts.

FLU VACCINE

Question: This year was the first to include funding for a permanent influenza immunization program. Yet, there are many members of the scientific and lay communities who doubt the safety and efficacy of any flu vaccine, feelings which were compounded by the bad image of the swine flu program.

With this in mind, would you please give us some facts as to what the incidence of the Russian Flu disease is in the United States?

Answer: Russian influenza virus was first isolated during the present season in September 1978. The first widespread activity occurred in California beginning in November. Since then, 48 States and Territories have reported isolation of the Russian-type virus. Widespread activity has occurred principally in the Western, Midwestern, and Southeastern States. Influenza this year has occurred almost entirely in the less than 27 age group. A number of schools have closed for a few days because of influenza like illness.

Question: How many deaths are directly related to Russian Flu?

Answer: As indicated in the answer to a previous question, most influenza activity this winter has been associated with "Russian" types of influenza (H1N1); no overall excess mortality has been observed in the United States. However, one child who died with Reye's Syndrome had evidence of infection with the H1N1 influenza virus. Epidemiologic data currently being collected indicate that another 12 deaths may be associated with the H1N1 virus.

Question: What long-term medical evidence and clinical trials do we have to prove the efficacy of Russian Flu vaccine and the fact that there are no side effects?

Answer: Field trials carried out during the summer of 1978 demonstrated that side effects from the Russian flu vaccine are infrequent and mild, usually local, and affecting less than 5 percent of recipients. Since then, the Adverse Reaction Monitoring System

at CDC has received only 55 reports of illness following influenza vaccination, none of which represent unexpected illness.

Studies of vaccine efficacy are underway at this time. Preliminary investigation during an outbreak at Ft. McClellan, Alabama, indicated an efficacy of 50-60 percent following one dose of vaccine. This is consistent with the results of clinical trials, which suggest that efficacy following the recommended two doses would be 80-90 percent. Other investigations are being completed, and longer term prospective studies are planned.

Question: Is "Reyes Syndrome" a consequence of Russian Flu?

Answer: In the past, outbreaks of Reye's Syndrome have been associated epidemiologically with influenza B. Cases of Reye's Syndrome have been associated only sporadically with influenza A of the H3N2 (e.g., Texas) strain. This year is the first in which we have evidence of an association between Russian flu (which is a type A influenza) and outbreaks of Reye's Syndrome. This association is currently under intensive investigation.

GLOBAL INTELLIGENCE SERVICE

Question: As you know, last year the Committee directed you to strengthen and expand the work of your Global Intelligence Service.

What has been the result of the Committee's directive and what effort should be made in this area in the future?

Answer: CDC provided epidemiologic training to 75 persons representing several middle Eastern countries in January 1979. We will begin training four Latin American epidemiologists under the auspices of the Pan American Health Organization (PAHO) in July 1979. We have also reached agreement in principle with the World Health Organization to assign one epidemiologist to each of two countries in that organization's South East Asia region (SEARO) beginning late in 1979 to develop two national EIS programs as the first state of a broader program.

BUILDINGS AND FACILITIES

Question: You are asking for an increase of from $1.9 million in '79 to $11 million in '80 for your Buildings and Facilties Account.

Please give us a breakdown and a description of why this account and the funding of these programs has to be done immediately and cannot wait for the future years?

Answer: The funds are needed in four areas. First, the Center has the responsibility for the maintenance of approximately 1,750,000 square feet of laboratory, special purpose, and office space and many of the facilities have been in service over 35 years. $1,431,000 is required to maintain and/or adapt the facilities to current needs. Examples of expenditures are roof repair and replacement, improving obsolete fire alarm system, road repairs, install standby generator for the Clifton Road, Atlanta, Georgia facility, replace 1,000 ton absorption chiller, and other equipment as it wears out.

Second, $6,600,000 is required to construct a much needed 35,000 net square foot addition to the NIOSH research facility in Cincinnati, Ohio. This addition is in lieu of constructing a new research laboratory. The increased research space is required by NIOSH's increased responsibilities for providing safe and health worksites for the American worker.

Third, the Center conducted a thorough investigation of the circumstances surrounding two work related deaths of two employees. The investigation revealed the need for laboratory safety improvements to protect the Center's laboratory workers and the surrounding community. Examples of these safety improvements are:

(1) Procuring and installing necessary safety equipment such as biological safety cabinets, laminar flow hoods, chemical fume hoods, air handling equipment, autoclaves, controlled access equipment, and other peripheral safety equipment.

(2) renovating and improving the toxicology laboratory;

(3) renovating and improving the smallpox laboratory;

(4) renovating Rickettsia laboratories;

(5) renovating existing space for a high security laboratory to handle suspected botulism specimens and other highly toxic infectious materials;

(6) modifying space for safe handling of areosol challenge studies;

(7) modifying existing arbovirus laboratories;

(8) purchasing approximately 9 residential acres contiguous to the Center's present maximum security laboratory.

Fourth, $105,000 is requested to suport the Federal Government's goal of conserving energy. The expenditure of $105,000 will result in estimated annual savings of $39,000 after the completion of three projects: retrofit incinerator to recover heat for water heating; install programmable start-stop systems for air conditioning in Cincinnati, Ohio and Morgantown, West Virginia.

The increases are needed in 1980 to continue to provide the safe facilities necessary to carry out the responsibilities placed on the Center by Congress and the Administration.

NATIONAL OCCUPATIONAL HAZARDS SURVEY II

Question: What are the plans for a National Occupational Hazards Survey II?

Answer: National Institute for Occupational Safety and Health (NIOSH) conducted the nation's first comprehensive survey of workplace hazards from 1972-1974 by deploying 20 engineers in a sample of nearly 5,000 facilities. This National Occupational Hazard Survey (NOHS) data base has continued to yield valuable results to NIOSH research activities, and is continually utilized by other Federal agencies, State and local governments, the private sector, and academics.

The NOHS data base is now more than six years old. The mix of industry types has changed, new process technologies and control methods have been developed, and a new generation of trade name products has emerged. These changes in the environment, coupled with a continuing need for current data on workplace exposures, make it essential to conduct a second national survey.

Preliminary planning for NOHS II has focused on 11 major tasks:

(1) developing a mission statement.

(2) convening a conference to identify data needs for anticipated significant users.

(3) constructing a representative sample of industrial facilities.

(4) specifying the nature of the data to be collected at the worksite.

(5) recruiting and training the surveyors.

(6) conducting the survey.

(7) updating trade name ingredient data.

(8) constructing the data base.

(9) analyzing the data.

(10) disseminating the results.

(11) working with other agencies in coordinating this information with other Federal data bases.

Question: What is the National Institute of Safety and Health (NIOSH) doing to respond to the GAO suggestions about improving the Health Hazard Evaluation Program?

Answer: In the last several years NIOSH has taken a close look at the Health Hazard Evaluation (HHE) program through two studies. The GAO report complements these studies and has been of assistance in making further improvements to the program.

In general, we concur with the GAO recommendations and have reevaluated several aspects of the HHE program and initiated appropriate changes. As an example, in order to improve the timeliness for issuing reports, medical resources available to the program have been increased and the review process streamlined.

The Department concurs that the program should be known to all employers and employees. As additional resources can be made available to the program, increased publicity will be given to it. The President's budget includes $3.75 million in FY 1980 for expansion of the HHE program, an increase of $2.15 million over the FY 1979 level. In addition, 20 new positions for NIOSH, all of which will be used for the HHE program.

BERYLLIUM AND CANCER

Question: In February, 1978, eight scientists specializing in occupational medicine and public health, criticized the scholarship and objectivity used by NIOSH in preparing a study which linked beryllium to cancer. In a letter to Secretary Califano, the scientists said that the "Human and animal studies cited by NIOSH and OSHA in the recently concluded beryllium hearings are shocking examples of the shoddy scholarship and questionable objectivity utilized in making important national regulatory decisions." In response to these criticisms, Secretary Califano convened a group of scientific experts to review the quality and objectivity of the NIOSH study. On November 10, 1978, the committee reported to the Secretary of Labor that beryllium does cause cancer in animals and humans and that worker exposure to the metal should be tightened.

What effect has this publicized criticism had on NIOSH's standing as a scientific organization?

Answer: It is difficult to assess the lasting impact publicized criticism of the quality of NIOSH's research will have on the standing of the Institute as a scientific organization. Such criticism, often blown out of proportion, is frequently directed at scientists in regulatory agencies or in agencies that must be responsive to regulatory needs. A number of the scientists involved in this criticism were consultants to the beryllium industry. It may be assumed there will be some adverse residual effect even though such criticism is subsequently found to be unsupported. It can be assumed that such criticism will continue as the Institute addresses research To be used as the basis for regulatory action. The Institute has taken or is in the process of initiating steps designed to reduce the potential for such criticisms.

A position for a Deputy for Scientific Affairs is to be established in the Institute Director's office and the incumbent will be responsible to develop even more effective scientific review systems within the Institute. Greater interaction will be developed between NIOSH's scientists and those at the NIOSH supported Educational Resource Centers (ERCs), including involvement by the ERCs in the Institute's peer review systems. NIOSH will also be making a greater commitment to basic research than has been made in the past. In

addition, the NIOSH research grant program will be used to encourage highly qualified investigators from all relevant disciplines to address research problems in occupational health.

SCIENTIFIC MANPOWER

Question: Recognizing the lack of qualified scientific manpower in the areas of environmental and occupational health, Congress authorized increases in appropriations for NIOSH training grants in fiscal years 1978 and 1979.

How many training grants have been awarded?

Answer: Prior to Congress providing NIOSH with an increase of $1. million dollars in late FY 1977 and an additional net increase of $1.5 million dollars in FY 1978 and an additional $2.4 million dollars in FY 1979 for the training grant program, NIOSH had been awarded approximately 25 training grants per year for individual training programs. These grants resulted in approximately 1,200 individuals - physicians, nurses, industrial hygienists, safety specialists - being provided graduate level training in occupational safety and health annually. These additional funds provided by Congress have been utilized to significantly increase the number of skilled professionals in the field of occupational safety and health through the funding of what NIOSH calls Educational Resource Centers (ERC). These Centers are universities which provide coordinated multidisciplinary and multilevel long-term training and continuing education for occupational safety and health manpower. To date, 11 of these Centers have been funded. By the end of this year we expect to have awarded grants to 12 of those institutions.

Question: On what criteria are the awards based?

Answer: NIOSH uses three major criteria in awarding ERC grants. We evaluate the ability of the applicant to achieve the goals of training occupational safety and health professionals. We evaluate the size of the occupational safety and health problem reflected by the concentration of workers and the type of industry in the area. We also strive for geographic spread in the location of the Centers.

Question: Is there any evidence that the gap between supply and demand of these valuable scientists is narrowing?

Answer: In regard to the gap between supply and demand, a recently completed NIOSH manpower survey of occupational safety and health professionals has shown that there are presently approximately 80,000 staff people working in the occupational safety and health field, and that the demand for new hires will be approximately 5,000 per annum over the next few years. NIOSH estimates that in FY 1979, through NIOSH's direct/indirect training program, and through the training grants programs, approximately 5,000 professionals will receive training. In future years this number, which represents a four-fold increase over our output prior to FY 1977, should increase even further as these Educational Resource Centers improve upon their continuing education and outreach programs.

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MINE SAFETY

Question: Under the Mine Safety and Health Act of 1977, the National Institute for Occupational Safety and Health is now responsible for mine safety and health research. The Fiscal Year 1979 budget included $1.5 million to plan for additional laboratory space at the Appalachian Laboratory for Occupational Safety and Health.

What progress has been made in planning for these additional facilities so that your added responsibilities may best be met?

Answer: In December of 1978 a program of requirements was completed for this additional facility. A contract for the architectural and engineering design for this addition is now under negotiation and will be awarded by the end of March. The design should be completed by October, 1980.

CARCINOGENS REGULATION

Question: In your 1977 publication, Carcinogens-Regulation and Control (DHEW-77-205), a substance was considered to be a carcinogen if properly designed studies show that exposure to the chemical causes cancer in: Humans; two different animal species (mammals); one animal species if the results are duplicated in separate studies; and one animal species if the results are supported by multi-test evidence of mutagenicity (short-term tests). 1/

Is this your current criteria for determining occupational carcinogens?

Does it differ from the Occupational Safety and Health Administration's criteria set forth in its generic carcinogen policy proposal (42 FR 54132-54256)?

1/ Carcinogens-Regulation and Control. NIOSH PHS DHEW 77-205, August 1977.

Answer: The quotation from the August 1977 technical assistance publication, "Carcinogens-Regulation and Control", DHEW Publication No. (NIOSH) 77-205, relates to the proposed OSHA definition of a chemical as a carcinogen for regulatory purposes. DHEW has not yet finalized a formal policy on the definition of a carcinogen, but NIOSH supports the overall concepts contained in the OSHA definition.

PERSONNEL

Question: During the Fiscal Year 1978 it was reported that a number of key personnel had left the Institute.

Have these positions been filled?

Answer: During 1978, 26 employees in key positions - at Branch Chief level or above - had left the Institute. At this time, 16 of these vacancies or 61 percent have been filled.

Question: Is the Institute working at capacity?

Answer: As of March 1, 1979, the Institute's "on board" employment was 874. NIOSH has a total of 913 budgeted positions and our 1979 employment ceiling is 880. Therefore, as of March 1, our employment was 99.4 percent of our total ceiling.

Question: What, if any, problems resulted from the lack of leadership in the Institute for a number of months?

Answer: The lack of a Director for an extended period of time always creates problems within an organization. In an effort to minimize the problems the Center assigned some of its top scientific/medical administrators to serve as Acting Director of NIOSH for varying periods during this time. The success of this move is evidenced in the fact that the Institute was able to accomplish practically all of its objectives as planned for the year. Now, with Dr. Robbins in the Director job NIOSH should get back in full stride.

HEALTH EDUCATION - NIOSH

Question: For nearly nine months, NIOSH was without a Director. Now, I understand, Dr. Robbins, formerly with the Colorado Health Department, has been appointed as Chief.

Explain the difference between your program, the Environmental Institute, OSHA, EPA and the Cancer Institute?

Answer: All of the agencies indicated have one or more responsibilities or activities in the area of occupational or environmental health. NIOSH and OSHA have legislatively mandated responsibilities to deal with the occupational health and safety problems of workers. NIOSH primarily is a research organization conducting basic and applied research directed towards the development of recommended occupational safety and health standards for protection of the health and welfare of American workers. OSHA is a regulatory agency responsible for promulgation and enforcing occupational standards in the industrial environment. The National Institute of Environmental Health Sciences (NIEHS) and the National Cancer Institute (NCI) are research institutes within the National Institutes of Health. NIEHS currently conducts basic research with respect to mechanisms of action of environmental pollutants or contaminants, but has no legislative mandate in occupational safety and health. National Cancer Institute is responsible for conducting basic and applied research with respect to the cause, prevention and cure of cancers of all types. National Institute for Occupational Safety and Health is specifically concerned with occupationally related cancer, while NCI has a broader interest in cancer in general. Environmental Protection Agency is primarily a regulatory agency responsible for developing and enforcing standards designed to protect the nation's environment (air, water, etc.) from excessive contamination and for the protection of the general population from toxic hazards.

PROGRAM EMPHASIS

Question: In light of the Occupational Safety and Health Administration's plan to place emphasis on the health hazards in the work place, will NIOSH be taking this same approach and de-emphasizing its safety research?

Answer: In fiscal year 1979, NIOSH will spend approximately $3 million for occupational safety research, standards development, manpower development, and technical assistance activities. This represents less than 5 percent of NIOSH's annual budget, the remainder being devoted to occipational health activities. In fiscal year 1980 the amount spent on occupational safety will remain approximately the same. Therefore, the percentage of NIOSH's budget spent on safety will drop to less than 4 percent.

This should not be interpreted, however, as an effort by NIOSH to deemphasize safety research. NIOSH's safety research program is just in its infancy; the Division of Safety Research having been established just over a year ago. Over the last six months, the Division has been developing a long range plan for safety research with assistance from OSHA and representatives from organized labor, industry and the universitites. As a consequence of this effort, NIOSH now plans to concentrate its efforts on the development and demonstration of effective control measures for the reduction of the six occupational accident types which are resulting in the highest workmens' compensation costs. By the end of this next decade, we hope to be able to save the taxpayers between $1-2 billion per annum in workmens' compensation costs resulting from occupational accidents and injuries. We are planning to place greater emphasis on our safety research program in the future.

RESEARCH STUDIES

Question: Does the budget request include funds to implement the research studies mandated by the Mining Safety and Health Act and the Black Lung Benefits Reform Act?

Answer: Our FY 1980 request includes approximately $8 million for implementation of the mandated studies and for conducting health hazards evaluations in mines. We received in late Fiscal Year 1979 $200,000 from the Department of Labor to conduct the medical portion of the respiratory disease study mandated by the Black Lung Benefits Reform Act. The report of this study is due to be completed in August of this year.

ADDITIONAL POSITIONS

Question: Does the budget you submitted request additional positions for these mining research activities?

Answer: No. Our request includes 20 positions for expanding our program of health hazard evaluations of general industry.

BUDGET REQUEST VS. RECOMMENDATIONS

Question: How does the budget request for mining research activities compare with the recommendations submitted to the Committee in the Richmond Report?

Answer: The Richmond Task Force Report supported program growth that would include the addition of 225 staff and $15 million dollars in additional funds.

MORGANTOWN LABORATORY SPACE

Question: In your testimony last year you stated that planning for additional laboratory space for the Morgantown facility would be required to enable the Institute to assume the responsibilities assigned as a result of the passage of the Mine Safety and Health Act.

What action have you taken?

Answer: For FY 1979 NIOSH received an appropriation of $1.5 million dollars for the design of an additional wing for the Morgantown facility. A program of requirements for this facility was completed in December of this year. We have advertised and are presently negotiating a contract for the architectural and engineering design of this addition. It is anticipated that the contract will be awarded by the end of March. The design of the new wing should be completed by October 1980.

CONSTRUCTION COST

Question: How much do you estimate the construction of this building will cost and how long will it take?

Answer: Our preliminary estimates are that this facility will cost approximately $20 to $25 million dollars. Construction will take approximately two years.

ADDITIONAL PEOPLE

Question: How many additional people will this addition hold?

Answer: As outlined in the Richmond Task Force Report which was submitted to the Chairman of the Committee last June, the planned addition will house approximately 300 staff who will be involved in metal/nonmetal mining activities and safety research.

TAFT BUILDING

Question: I see on Page 117 of your justification that you are requesting $6.6 million for the Taft Building in Cincinnati, Ohio. What is that for? Are you requesting any construction funds for Morgantown?

Answer: In addition to the expansion of the NIOSH facility in Morgantown, the Richmond Task Force recommended that NIOSH consolidate its activities in Cincinnati into the facilities at Ridge Avenue

and the Taft Center. The $6.6 million is for a 35,000 square foot addition to the Taft Center facility to accommodate additional program staff required over the next five years in Cincinnati.

We are in the process of awarding an architectural and engineering contract for planning a new wing for our Morgantown facility. Decisions about construction funds will be made as part of the 1981 ZBB process.

VENEREAL DISEASE

Question: Last year you reported that for the first time in 20 years there was a decline in the incidence of both syphilis and gonorrhea.

Has this decline continued and what prospects do you see for the future?

Answer: Unfortunately, this trend has not continued. Reported cases of gonorrhea increased 1.3 percent and reported cases of recently acquired syphilis increased 0.8 percent during fiscal year 1978. The increase in reported cases of gonorrhea is largely due to a 3.0 percent increase in women which resulted from intensified case detection among high-risk groups. Although this upward trend has continued for the first quarter of fiscal year 1979, it is felt to be a temporary setback for control efforts and the trend for both diseases will stabilize or decline slightly during this fiscal year.

Question: What progress can you report in the battle against the spread of penicillin-resistant gonorrhea?

Answer: Since penicillinase-producing Neisseria gonorrhoeae (PPNG) was identified in March 1976, a total of 508 cases from 31 States, the District of Columbia, and Guam have been reported. California, the only State that has experienced one or more cases each month since surveillance began, reported 289 (56.9 percent) of the cases. About one-half of the remaining cases were imported or linked to imported cases. Although the remaining PPNG cases may reflect spread within the United States, no definite endemic focus of PPNG has been identified.

SUBCOMMITTEE RECESS

Senator MATHIAS. The subcommittee will stand in recess until 10:30 tomorrow morning when we will hear the budget request for NIH.

[Whereupon, at 4 p.m., Tuesday, February 27, the subcommittee was recessed, to reconvene at 10:30 a.m., Wednesday, February 28.]

DEPARTMENTS OF LABOR AND HEALTH, EDUCATION, AND WELFARE AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 1980

WEDNESDAY, FEBRUARY 28, 1979

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
Washington, D.C.

The subcommittee met at 10:10 a.m., in room S-128, the Capitol, Senator Warren G. Magnuson (chairman) presiding.

Present: Senators Magnuson, Hatfield, and Schweiker.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

NATIONAL INSTITUTES OF HEALTH

STATEMENT OF DR. DONALD S. FREDRICKSON, DIRECTOR

ACCOMPANIED BY:

DR. THOMAS E. MALONE, DEPUTY DIRECTOR
NORMAN D. MANSFIELD, DIRECTOR, DIVISION OF FINANCIAL MANAGEMENT
BRUCE S. WOLFF, DEPUTY ASSISTANT SECRETARY FOR LEGISLATION (DESIGNATE)
WILFORD J. FORBUSH, DEPUTY ASSISTANT SECRETARY, BUDGET

1979 APPROPRIATION AND 1980 BUDGET REQUEST

Chairman MAGNUSON. This will be the first of four sessions on NIH.

We will start off with an overview.

We will also try to go as far as we can on an overview of the Cancer, Heart, and Dental Institutes, as well as the Director's Office.

Before you start, let't get the proper figures.

Ten years ago for fiscal 1970, we appropriated $1 billion for all of NIH.

The President's request for fiscal 1980 is $3,172,430,000. That is over three times the appropriation in 1970.

Now I realize that inflation has been at work here, but any way you cut it, we've come a long way in these 10 years.

In fiscal 1979, the NIH level was $3,189,529,000.

The fiscal 1980 request is for a net decrease of $17,099,000 over last year.

We are ready, Dr. Fredrickson for you. I want to encourage all the witnesses here not to hestitate to jump in anytime during these

four sessions, if they have something to contribute to the topic under discussion.

So you can introduce your colleagues, Dr. Fredrickson.

Dr. FREDRICKSON. Thank you very much, Mr. Chairman.

Chairman MAGNUSON. Unless you have something?

Senator HATFIELD. No.

Dr. FREDRICKSON. It is a pleasure for us, the collected Directors of Institutes and Divisions of the National Institutes of Health, and for myself, to appear before you today on discussion of the 1980 budget request.

We have a seating chart, Mr. Chairman.

If you wish we can go around the table.

Chairman MAGNUSON. Well, we can just put who is here in the record.

Dr. FREDRICKSON. All right. Very good.

I think there is only one variation in that chart, Mr. Chairman.

Chairman MAGNUSON. Like everything else in NIH, I can't understand it.

Dr. FREDRICKSON. Our job is to make it as understandable as possible, sir.

Chairman MAGNUSON. They can identify themselves when they speak up.

Dr. FREDRICKSON. All right, sir.

PREPARED STATEMENT

Mr. Chairman, I have a statement which I would like to submit to the record, if you have no objection, and to comment upon it, and summarize it briefly, for you.

[The statement follows:]

STATEMENT OF DR. DONALD S. FREDERICKSON

I am here to discuss with you today the 1980 budget request for the National Institutes of Health.

Although the figures in this budget are approximately identical to the 1979 appropriation, I come before the Subcommittee to assure you that the various programs of the NIH will be able to continue the level of excellence you have come to expect of us.

Maintenance of this level in a time of severe budgetary constraints represents a firm commitment by the Administration to the notion that the individual and societal costs of disease and disability can best be reduced through development of new approaches to prevention and treatment--approaches that depend in large measure on elucidation of the mechanisms underlying fundamental biological processes and an understanding of what happens when these fail or are altered to produce disease.

Maintenance of a level budget will impose difficult choices in the management of the biomedical research enterprise, and I am pleased to report that we are making significant progress in our ability to deal with some of the choices we face.

We now classify all of our programs as they relate to the four areas comprising the NIH mission to improve the Nation's health. The first of these, termed the science base, accounts for 74 percent of the overall 1980 NIH budget request. It is science after all--the acquisition of new knowledge--which provides us with the tools we require to develop the ultimate means to reduce health care costs through preventing and treating more efficiently disease and disability. Thus, the manner in which research results are put to use comprises our second category--application--which depends intimately and entirely upon the success of our research programs. The third category, which we term "transfer", is an essential function of NIH and simply means that, once we know something important, we must make sure that the rest of the world knows about it too, and as soon as possible. It is especially important that physicians and health professionals put into use the most advanced methods available without delay. The fourth category, training, is, of course, the means by which the NIH and the Nation can continue the high quality of research for which we are acclaimed.

I cannot over-emphasize how absolutely vital the continued support of NIH's science base must be. I would like to take just a few moments to illustrate some of the recent advances in biomedical research and how this new knowledge is continually offering us potentially beneficial applications. The history of science is replete with examples to support this view. Recent advances in the use of recombinant DNA techniques have yielded new insights into the structure and regulation of genes, offering the possibility of commercial production of scarce biological products, such as insulin and growth hormone. It has moved us several steps closer to knowing the underlying causes of cancer, and to realizing the effective treatment of some genetic diseases. "Basic" research in receptor sites--characterizing the interaction of hormones and cell surfaces--holds promise for the treatment of endocrine diseases such as diabetes. And investigation of the differences between normal and cancerous cells, while directed at the most fundamental biological processes, has significant implications for the diagnosis and prevention of cancer.

Certain elements of the science base deserve special mention. As Congress has recognized in recent hearings and reports, the primary mechanism for knowledge development is the investigator-initiated research project. Approximately 43 percent of the 1980 funds requested will support extramural research projects, allowing us to fund about 20 percent of approved competing grant applications. Supplementing the individual and program research projects are the research centers, where multidisciplinary interaction and support enable us to focus research in specific areas, such as heart disease and cancer. I share this Committee's concern that NIH grant programs be supported by a strong peer review system, and I am pleased to report the addition of four badly needed new study sections whose charters have recently been signed by Secretary Califano.

Our own intramural research program, conducted mainly in laboratories and clinics on and near the NIH campus, engages the efforts of approximately 60 percent of our staff. Evaluations of this program have repeatedly shown that intramural scientists' contribution to the science base far exceeds that which one would expect, based on their numbers. A recent evaluation shows the output of "most cited papers" between 1961-1975 by NIH intramural scientists to have exceeded by far any university in the world. There is no question that this select group of highly competent individuals, which includes four Nobel laureates, represent a major national asset, providing leadership to the biomedical research community and serving as a valuable resource to the extramural program staff.

The Clinical Center on the NIH campus provides unique opportunities for bringing the intramural science base to the point of application, a capacity that will be greatly enhanced by completion of the Ambulatory Care Research Facility. The final funding for the ACRF was provided last year, and construction is progressing smoothly; we look forward to its opening in 1982.

The application of research findings and development of interventions aimed at specific problems of health and disease represents the next step in the research continuum. Among the more exciting topics to be explored are development of systemic anti-viral agents and application of positron emission transverse tomography (PETT) for diagnosis of intracranial lesions. Also planned are several major clinical trials, including a joint effort between NHLBI and NIA to determine the effectiveness of lowering blood pressure in the elderly.

In recent years we have made significant progress in fostering the transfer of research findings to the health care delivery system. The Office of Medical Applications of Research, now officially established, serves as the focal point for NIH transfer activities, as well as a link to the broader mandate of the new National Center for Health Care Technology. One of the key elements in this process is the development of consensus about treatment modalities. Over a dozen conferences have been held on a number of topics for this purpose and several more are planned. In keeping with our heightened interest in prevention, we are including a conference on antenatal diagnosis which is scheduled for next week. The proceedings of these meetings are disseminated to both scientists and practicing physicians and to further inform the general public.

The training of biomedical investigators remains one of the most critical activities supported by the NIH. All of our research training programs have now been consolidated under the National Research Service Awards program, and recent amendments to that law have done a great deal to make these awards more attractive to young scientists. The NIH has put forth a great deal of effort in the past year to develop a training policy truly responsive to the Nation's needs for the training of research personnel, as recommended by the National Academy of Sciences. The 1980 budget contains a modest increase for research training, which will be directed primarily toward training of epidemiologists and environmental toxicologists, who are needed to implement the new incentives in disease prevention. The budget request will provide for the training of approximately 10,900 investigators, an increase of some 375 over the current year's program.

Within the budget request, several areas of emphasis have been identified. Foremost among these is the Secretary's initiative in prevention. Much of the NIH program is, at least indirectly, related to prevention, because the ultimate objective of most biomedical research--the understanding of life's most fundamental processes--will provide us with the means to prevent disease and disability. The redirection of funds within the budget will permit more rapid exploitation of certain high-priority areas, particularly those which lend themselves to enhanced cooperation and coordination among the Institutes of NIH and between NIH and other agencies. For example, toxicology research will be expanded to include additional studies of the effects of environmental agents and pollutants on human health, and the training of additional environmental toxicologists. This expansion will take place within the newly established National Toxicology Program which will provide coordination, under the leadership of the Director of the National Institute of Environmental Health Sciences, of all the Department's programs in toxicology.

International health is another area to be highlighted, focusing primarily on tropical disease and infectious diseases of international concern. The National Institute of Allergy and Infectious Diseases will serve as a focal point for international collaboration between the United States and foreign investigators.

As mandated by the Congress last year, diabetes continues to be an area of strong emphasis in many of the NIH Institutes. Recently, I directed the National Institute of Arthritis, Metabolism, and Digestive Diseases to assume the leadership role in coordination of all NIH diabetes research activities. It is our hope that this will serve as a model for management of the many crucial research efforts that cut across Institute lines. The NIH commitment to diabetes research will continue to be strengthened in 1980, and the budget request includes an estimated $125 million for diabetes research.

Nutrition is another area of trans-NIH interest which offers great promise for the management and possible prevention of many disease states. Its importance is highlighted by the many Congressional mandates directed at NIH and other agencies. Research in nutrition continues to shed light on ways in which the body utilizes nutrients and how certain dietary substances may be related to diseases with a high incidence in the American population. We are expanding our support of clinical nutrition research units to include core grants for shared facilities combining research, training, and service. We expect to have several such units underway by the end of the year.

In conclusion, Mr. Chairman, the NIH request for FY 1980 is $3,172,430,000. In addition, we have before you a supplemental request of $10,713,000 for the NICHD population research program and a proposed rescission of $37,000,000 for the NICHD Research Facility. We will be pleased to try to answer any questions that you or your colleagues may have.

BUDGET REQUEST

Chairman MAGNUSON. Well, why don't you go ahead with the statement if it is a short one.

Dr. FREDRICKSON. We are here today to discuss with you the 1980 budget request for the National Institutes of Health.

Although the figures in this budget are approximately identical to the 1979 appropriation, we come before you to assure you that the various programs of the NIH will be able to continue the level of excellence that you have come to expect of us.

Chairman MAGNUSON. Somebody open those doors.

Dr. FREDRICKSON. This is a time of severe budgetary constraints and maintenance of this level of funding represents a firm commitment by the administration to the notion that the individual and societal costs of disease and disability can best be reduced through the development of new approaches to prevention and treatment—approaches that depend ultimately on new knowledge, knowledge that generally must be acquired through research.

Maintenance of a level budget will impose difficult choices in the management of the biomedical research enterprise, and I am pleased to report that we are making significant progress in our ability to deal with some of the choices we face.

We now classify all of our programs as they relate to the four areas comprising the NIH mission to improve the Nation's health.

Chairman MAGNUSON. Where are we now?

Dr. FREDRICKSON. Right at the bottom.

The first of these four categories, termed the science base, accounts for about 74 percent of the overall 1980 NIH budget request. The science base is primarily directed at the acquisition of new

knowledge, which provides us with the tools we require to develop the ultimate means to reduce health care costs through preventing and treating more efficiently disease and disability.

Thus, the manner in which research results are put to use comprises our second category—application—which depends intimately and entirely upon the success of our research programs. The third category—transfer—is an essential function of NIH and simply means that, once we know something important, we must make sure that the rest of the world knows about it too, and as soon as possible. It is especially important that physicians and health professionals put into use the most advanced methods available without delay. The fourth category—training—is, of course, the means by which the NIH and the Nation can continue the high quality of research for which we have been acclaimed.

SUPPORT OF SCIENCE BASE

I cannot overemphasize how absolutely vital the continued support of NIH's science base must be. I would like to take just a few minutes to illustrate some of the recent advances in biomedical research and how this new knowledge is continually offering us potentially beneficial applications. The history of science is replete with examples to support this view. Recent advances in the use of recombinant DNA techniques have yielded new insights into the structure and regulation of genes, offering the possibility of commercial production of scarce biological products, such as insulin and growth hormone. It has moved us several steps closer to understanding the underlying causes of cancer, and to realizing the effective treatment of some genetic diseases. "Basic" research in receptor sites—characterizing the interaction of hormones and cell surfaces—holds promise for the treatment of many endocrine diseases such as diabetes. And investigation of the differences between normal and cancerous cells, while directed at the most fundamental biological processes, has significant implications for the diagnosis and prevention of cancer.

Certain elements of the science base deserve special mention. As Congress has recognized in recent hearings and reports, the primary mechanism for knowledge development is the investigator-initiated research project. About 43 percent of the 1980 funds requested will support extramural research projects, allowing us to fund about 20 percent of approved competing grant applications. Supplementing the individual and program research projects are the research centers, where multidisciplinary interaction and support enable us to focus research in specific areas, such as heart disease and cancers. I share this committee's concern that NIH grant programs be supported by a strong peer review system, and I am pleased to report the addition of four badly needed new study sections whose charters have recently been signed by Secretary Califano.

Our own intramural research program, conducted mainly in laboratories and clinics on or near the NIH campus, engages the efforts of approximately 60 percent of our staff. Evaluations of this program have repeatedly shown that the contribution of intramural scientists to the science base far exceeds that which one would

expect, based on their numbers. A recent evaluation shows the output of "most cited papers" between 1961–75 by NIH intramural scientists to have exceeded by far any university in the world. There is no question that this select group of highly competent individuals, which includes four Nobel Laureates, represents a major national asset, providing leadership to the biomedical research community and serving as a valuable resource to the extramural program staff.

The Clinical Center on the NIH campus provides unique opportunities for bringing the intramural science base to the point of application, a capacity that will be greatly enhanced by completion of the ambulatory care research facility now under construction. The final funding for the ACRF was provided last year and construction is progressing smoothly; we look forward to its opening in 1982.

APPLICATION OF RESEARCH FINDINGS

The application of research findings and development of interventions aimed at specific problems of health and disease represents the next step in the research continuum.

Among the more exciting topics to be explored are development of systemic antiviral agents and application of positron emission transverse tomography (PETT) for diagnosis of intracranial lesions.

Chairman MAGNUSON. Doctor, the last time you were here, you phrased this in lay language so that we could understand it.

Dr. FREDRICKSON. This is a new technique, Mr. Chairman, which involves the measurement of isotopes that will allow us to localize single molecules working in the nervous system.

Chairman MAGNUSON. That is a little better.

Dr. FREDRICKSON. I think it is better, too, Mr. Chairman. I apologize for that.

Also planned are several more major clinical trials, including a joint effort between the National Heart, Lung, and Blood Institute, and the National Institute on Aging, to determine the effectiveness of lowering blood pressure in the elderly.

TECHNOLOGY TRANSFER

In recent years we have made significant progress in fostering the transfer of research findings to the health care delivery system. The Office of Medical Applications of Research, now officially established, serves as the focal point for NIH transfer activities, as well as link to the broader mandate of the new National Center for Health Care Technology.

One of the key elements in this process is the development of consensus about treatment modalities. Over a dozen conferences have been held on a number of topics for this purpose and several more are planned. In keeping with our heightened interest in prevention, we are including a conference on antenatal diagnosis which is scheduled for next week. The proceedings of these meetings are disseminated to both scientists and practicing physicians and to further inform the general public.

RESEARCH TRAINING

The training of biomedical investigators remains one of the most critical activities supported by the NIH. All of our research training programs have now been consolidated under the National Research Service awards program, and recent amendments to that law have done a great deal to make these awards more attractive to young scientists. The NIH has put forth a great deal of effort in the past year to develop a training policy truly responsive to the Nation's needs for the training of research personnel, as recommended by the National Academy of Sciences. The 1980 budget contains a modest increase for research training, which will be directed primarily toward training of epidemiologists and environmental toxicologists, who are needed to implement the new initiatives in disease prevention. The budget request will provide for the training of approximately 10,900 investigators, an increase of some 375 over the current year's program.

AREAS OF EMPHASIS

Within the budget request, several areas of emphasis have been identified. Foremost among these is the Secretary's initiative in prevention.

Much of the NIH program is, at least indirectly, related to prevention, because the ultimate objective of most biomedical research—the understanding of life's most fundamental processes—will provide us with the means to prevent disease and disability. The redirection of funds within the budget will permit more rapid exploitation of certain high-priority areas, particularly those which lend themselves to enhanced cooperation and coordination among the Institutes of NIH and between NIH and other agencies. For example, toxicology research will be expanded to include additional studies of the effects of environmental agents and pollutants on human health, and the training of additional environmental toxicologists. This expansion will take place within the newly established national toxicology program which will provide coordination, under the leadership of the Director of the National Institute of Environmental Health Sciences, of all the Department's programs in toxicology.

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In conclusion, Mr. Chairman, the overall NIH request for 1980 is $3,172,430,000. In addition, we have before you a supplemental request of $10,713,000 for the NICHD population research program and a proposed rescission of $37 million for the NICHD research facility.

We will be pleased to try to answer any questions that you or your colleagues may have.

Chairman MAGNUSON. All right. That is a very good statement.

It seems to me, from the statement, that you are attempting to do more consolidation of your programs, instead of having one over here; and another thing over here, you are trying to put them together. For that, I compliment you.

I'm glad that you are doing it.

For instance, in the case of diabetes, you are trying to put all those programs together.

Dr. FREDRICKSON. Yes, we are, Mr. Chairman.

Chairman MAGNUSON. The question of cancer research cuts across all kinds of lines in our medical research.

The request for fiscal year 1980 is $3.172 billion.

SUPPLEMENTAL REQUEST

You have a supplemental request for the NICHD population research program.

When did that come up?

That $10 million was added after the budget was made up.

Dr. FREDRICKSON. No, Mr. Chairman, it is included in the 1979 column of the 1980 budget request.

Chairman MAGNUSON. It is included in this, isn't it?

Dr. FREDRICKSON. Yes. It is included in the 1979 budget figure that you have.

Chairman MAGNUSON. Then the budget figure would be $3.182 billion?

Dr. FREDRICKSON. No; the $10.7 million supplemental is for 1979, not 1980.

Chairman MAGNUSON. Or $3.2 billion, to be exact.

PROPOSED RESCISSION

Now, we have a rescission, and the House is now working on that rescission. I don't know what they've done with it.

The House subcommittee rejected the $37 million for the child health facility.

Dr. FREDRICKSON. Yes.

Chairman MAGNUSON. Do you have any recommendations on that rescission for us?

Dr. FREDRICKSON. Well, Mr. Chairman, it is——

Chairman MAGNUSON. I know it's the President's budget. I know that.

Dr. FREDRICKSON. Mr. Chairman, I can speak to that and give my personal answer.

I think that the President, in recommending this rescission, has attempted to put program before building, and I approve of that, in these times of fiscal constraint.

I am also concerned that this building, which has long been on our high priority list at NIH, is not the first, but rather the second of my own personal priorities. In my own mind, the first priority must be the renovation of some of the older laboratory buildings at NIH.

On the other hand, I am aware of certain advantages that should accrue to the Child Health and Human Development Institute if its research programs were consolidated under one roof instead of being spread out in the nine different locations where they are presently housed.

Chairman MAGNUSON. Well, we discussed that at some length with the Secretary, Monday.

Dr. FREDRICKSON. Yes.

Chairman MAGNUSON. We tried to separate the items and look at that as a separate item of construction and not say that if you get $37 million here you ought to put it over here or something.

Dr. FREDRICKSON. I agree with that. These things should be considered separately.

Chairman MAGNUSON. Now I can understand the administration's feeling about slowing up on construction.

This would leave, of course, available within the budget, $37 million which will have to be taken out of someplace.

FUNDING COMPETING GRANTS

All right, now, on page 3 of your statement, you say that approximately 43 percent of 1980 funds requested would support extramural research projects, allowing us to fund only about 80 percent of the approved competing grant applications.

Dr. FREDRICKSON. About 20 percent, Mr. Chairman.

Chairman MAGNUSON. Yes; 20 percent.

Dr. FREDRICKSON. Yes.

Chairman MAGNUSON. So 80 percent of the approved grant applications may not be funded; is that correct?

Dr. FREDRICKSON. That would be correct under this budget, Mr. Chairman.

Chairman MAGNUSON. And still the grants, the total grant funds that you have available for extramural research projects are 43 percent of the budget?

Dr. FREDRICKSON. Yes, they are.

INTRAMURAL RESEARCH

Chairman MAGNUSON. That would suggest that about 57 percent of the work is being done in-house out there, and 43 percent is going out in grants?

Dr. FREDRICKSON. Not exactly so, Mr. Chairman.

Chairman MAGNUSON. I wish you would clear that up. There is always a controversy up here as to how much you do in-house against how much you do outside.

Dr. FREDRICKSON. Yes. The amount that we do in-house, in terms of the total proportion of the NIH budget, remains about the same as it has been in the last 10 or more years.

That is to say, the extramural and the intramural programs have grown at virtually the same rate, the extramural slightly faster, by 1 or 2 percent.

The difference in this 43 percent from the total of 100 percent is due to the other mechanisms available for supporting research, aside from the research projects mechanism, which represents our single biggest budget item.

In addition to these investigator-initiated research grants, there are many other kinds of research grants for centers, for young investigators, special awards for international work, and, of course, research and development contracts, as well.

CONTRACT RESEARCH

Chairman MAGNUSON. Well, the big amount would be contract research, isn't it?

Dr. FREDRICKSON. Contract research is declining now at NIH, and represents now about—it would be, in the total budget that we have before us, about $428 million out of the $3 billion request.

Chairman MAGNUSON. How much would that be?

Dr. FREDRICKSON. About 13 percent.

Chairman MAGNUSON. Thirteen percent.

Dr. FREDRICKSON. About 80 percent of the total NIH budget is extramural.

Chairman MAGNUSON. Of the total?

Dr. FREDRICKSON. Yes.

PEER REVIEW

Chairman MAGNUSON. Now, when you make these grant applications, we relied in the past a great deal on a peer review system.

Dr. FREDRICKSON. That is correct.

Chairman MAGNUSON. The system has sort of fallen down, in my opinion, because there are so many vacancies on these commissions. People are not appointed to them. They work shorthanded. That is the complaint I have.

I asked the Secretary about that yesterday. We had a tremendous figure, 2,000 appointees or something like that.

Four hundred people haven't been appointed now.

What have you done to get that going, to get your review people on these commissions and get them working?

Dr. FREDRICKSON. There are two aspects of this, Mr. Chairman. Most of the vacancies are in the councils, which is the second tier of review. For the initial review, you recall, we have the study

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sections, the technical reviewers. All of their work must then be approved by the councils before we can fund research grants.

We have more vacancies in councils than in study sections. Our problems in study sections have been an inadequate number of these review groups. I did refer in my statement to the recent addition to our complement of four new study sections.

We have been working intensively with the department to reduce the delay in appointments to the councils, which is a serious problem. The Department is now very much aware of it, and they have taken some extraordinary steps to try to fill those vacancies as soon as possible.

Chairman MAGNUSON. You are talking about men on the outside that are very capable men. They have got good positions at different schools and universities in the health field, and they say, all right, we will be glad to get on this board or this council. I have submitted a couple of names. Not any more. And then they sit there. They don't know what is going to happen.

I had one call me the other day, he said I'm going to give this up. I said, I don't blame you. He's been on it 2 years.

It seems to me that you ought—the Secretary says they are getting at it, but he's talking about 2,000 appointees in the overall HEW, education and everything else. But you are getting down to about a couple of hundred of top people here. I would hope that you would pursue that.

Dr. FREDRICKSON. I am pursuing it quite vigorously, Mr. Chairman.

Chairman MAGNUSON. And then, also, the nurses are a little upset because these councils are made up of all doctors.

Did you ever think of putting a nurse on one?

Dr. FREDRICKSON. Not only have we thought of it, we have done it.

Chairman MAGNUSON. Not a nurse. Several nurses.

Dr. FREDRICKSON. Mr. Chairman, we have tried to do that, and I will give credit to the Department, that it is trying to make sure that women and minorities are well represented.

Chairman MAGNUSON. I'm not talking about women and minorities, so much, as I'm talking about nurses.

Dr. FREDRICKSON. Yes. I recognize that as a special problem.

Chairman MAGNUSON. There are some good male nurses, too, and good paramedics, and they are very valuable.

I was hoping you would go after that, and see if you can't start that moving.

Dr. FREDRICKSON. We certainly are broadening the membership, Mr. Chairman, particularly on the councils.

RESEARCH TRAINING

Chairman MAGNUSON. We have found up here over the years that training has always been sort of an orphan in the storm, and you are trying, as I understand it, to point out that that is one of the most critical activities you have in front of you, is training.

Dr. FREDRICKSON. I think that training is the key to the future of all science, Mr. Chairman. Trained investigators must continue to move in and conduct the research.

Chairman MAGNUSON. They are not making it as attractive as it used to be.

I am hopeful that there is enough for training in this budget.

Dr. FREDRICKSON. Mr. Chairman, our problem with regard to the dollar amounts available for training revolves most crucially around the question of stipends. We are not paying our trainees enough; and we are now requesting the Public Health Service to increase the stipends so these people have a living wage.

If we do that within the present training budget, we will have to have a drop of 15 or so percent in the total number of trainees.

Chairman MAGNUSON. You say that you have provided training for approximately 10,900 investigators, and that is only an increase of 375 over the current program.

Dr. FREDRICKSON. That is at the current stipend levels, Mr. Chairman.

Chairman MAGNUSON. What do you mean by stipend?

Dr. FREDRICKSON. The salary paid to the trainee. We pay a predoctoral student about $3,000 a year. We are able to pay a doctor $10,000, although he may come from an internship or a residency at a salary on an average of about $14,000.

That is one of our problems in attracting physicians into research as a career. And it is a very serious problem.

HIGH-PRIORITY AREAS

Chairman MAGNUSON. Now, the redirection of funds, you say, on page 6 of your justification, prevents a more rapid exploitation of certain high priority areas.

What do you mean by that? Can you identify those areas further?

Dr. FREDRICKSON. Yes. As you are well aware, with your experience in these scientific affairs, Mr. Chairman, science gets "hot" in certain areas at different times. Right now, the "hot" areas include toxicology and environmental health. There is a tremendous national need for new knowledge, particularly to provide the regulators with the basis for setting standards for exposure to environmental pollutants.

Other areas include recombinant to DNA. This is still a time when reproductive biology and endocrinology are particularly important, as we said last year. Immunology, virology, the whole field of genetics and cell biology, are only a few of the high-priority areas.

Each of these Institutes has its own areas of high-priority activity, Mr. Chairman, and I think each of them has important areas of opportunity which are identified. The individual Institute directors will be able to describe these to you.

Chairman MAGNUSON. When you think about high priorities—do you suggest that we add some money to those and take it away from some of those areas that don't have a high priority? How are we going to determine this?

Dr. FREDRICKSON. I think there are several ways that we meet high-priority demands, Mr. Chairman.

Chairman MAGNUSON. Well, I assume that when you developed your budget that you had put the high-priority areas in their proper place?

Dr. FREDRICKSON. Yes. We attempted to do that.

Chairman MAGNUSON. When you went down to present your budget to the Budget Director, or through HEW?

Dr. FREDRICKSON. That is correct.

Chairman MAGNUSON. Did they change them a great deal?

Dr. FREDRICKSON. Mr. Chairman, in all fairness, I think it is very difficult to do zero-based budgeting in a place like NIH. You have to decide if heart research is much more important than cancer research, and vice versa, a decision which is almost impossible to make. So you have to try to get within the Institute certain program selections. And we do this in two ways.

Chairman MAGNUSON. But what I'm saying is, you've got the separate Institutes. We have got to appropriate line items for these budgets. You have certain, what you say, are hot areas, as opposed to cooler areas. And looking over the whole business, you might say that cancer and heart are two hot areas, and you might want to add more there, and not add to some other places.

Dr. FREDRICKSON. We do try to make those decisions.

Chairman MAGNUSON. You make those decisions when you develop your budget?

Dr. FREDRICKSON. That is right. Also, the Institutes use program relevance to make decisions of priority within each of their grant programs.

First, grant applications pass the test of excellence by study section, and then the Institutes may use program relevance as an additional determinant for funding, in order to put the emphasis in a given area.

NATIONAL TOXICOLOGY PROGRAM

There are also special programs, such as the national toxicology program I mentioned, created to meet a special need.

Chairman MAGNUSON. Well, that is a very important program. Is there any overlapping on that?

We are just through talking about coal mining research. We put a lot of money into that. And then in the field of education, we put in more money, and the Labor Department, they are involved. OSHA is involved in research now with regard to the toxicology programs.

I'm wondering if we are not getting into a little overlapping. Of course, you contend that your group—a newly established program—is going to deal solely with research.

Dr. FREDRICKSON. That is true. We all have this problem of coordination. You will now find that about once a month, the leaders of the national toxicology program, the Director of the Cancer and the Environmental Health Institutes, the Administrator of EPA, the Commissioner of Food and Drug, OSHA's own Director, the Consumer Protection Agency, both regulators and researchers are sitting down together to determine, as a group, what are the highest priorities for chemical testing.

I think this is a small step forward, but an important achievement in coordination. I think it is the most efficient, economical

way to approach a problem that confronts many agencies. I think we have a real start.

Chairman MAGNUSON. A lot of that approach is based upon numerical research. Find a place where they make asbestos or something, and study what is happening to all the people there. And then they find out that something has happened to the people in that particular area.

Do those responsible for regulation then give it to you for research, and do you start in basically on some other items?

Dr. FREDRICKSON. Usually it is the other way around, Mr. Chairman. We determine that some substances are toxic, and the regulator's question is, how toxic? How much can we allow the public to be exposed to it?

Then we have to put the substance through rigorous testing to determine the levels of hazard. Trying to establish the amount of exposure that all of us should endure is one of the most important tests.

Chairman MAGNUSON. That is the point I make.

They could fix the amount, but you would have to get down to the cause.

Dr. FREDRICKSON. In order to test it, we have to know why something is toxic.

Chairman MAGNUSON. Yes. Then you are through with it, once you find the cause. I don't mean you are through with it. But, generally, you furnish the research that this sort of element is toxic and, therefore, shouldn't be used. And then they have to go out and determine how toxic it was, how many people were affected, and massive research, and things like that—not research, but numerically.

Dr. FREDRICKSON. That is quite correct. We do some of the epidemiology research, although much of it is done by other agencies. Our job is to provide the knowledge of why things are toxic and what can be done about it. We try to understand the effects on cells, tissues, and organs of the body.

But we must to be very much aware of all aspects of the problem so that we are sure that we put our money where the problems are most important. And I think we have taken a long first step in that kind of cooperative program.

Chairman MAGNUSON. You say that after you have determined that a certain substance is toxic, you are not through with it, but then you recommend that it not be used or something like that.

Dr. FREDRICKSON. That is correct.

Chairman MAGNUSON. All right. We can pursue that later when we get to the Institute.

COST EFFECTIVENESS

Doctor, in the opinion of yourself and the other directors, what are the most important advances in terms of cost effectiveness that you have seen take place in the last few years?

Dr. FREDRICKSON. I think the continuation and strengthening of the peer review system is an important factor in cost effectiveness. We have improved the conflict-of-interest procedures that cover advisors. We have attempted to take necessary action to redistrib-

ute the enormous extramural workload more evenly throughout the year, so that it does not suddenly peak at the end, which means we can have more effective management of our extramural programs.

In the contract area, we've tightened the procedures and the approval levels for justification of noncompetitive projects.

As part of this, I myself must now review each noncompetitive action in excess of $100,000, and the Assistant Secretary for Health must approve actions above $500,000.

We certainly have increased and sharpened NIH policies and procedures requiring outside peer review of research and development contracts.

We have simplified the current grant applications. We have shortened it so that it places less of a burden on both investigators and the reviewers, and we are improving the role of business management consultants in grant review.

These are just a few examples of how we have tightened our administrative processes to make our programs more cost effective.

Chairman MAGNUSON. What about monitoring the proposals in management?

Dr. FREDRICKSON. We continue to monitor these proposals carefully, to the extent that we have the administrative capability. I think we are trying to maintain our stewardship as well as possible in both the grant and contract areas.

Chairman MAGNUSON. Do you have an inspector general down there?

Dr. FREDRICKSON. We have an inspector general now in the Department, and, his office is very active in following up any problems.

Chairman MAGNUSON. How many people are there?

Dr. FREDRICKSON. I don't know what their total staff is Mr. Chairman.

We have added six accountants in the division of contracts and grants at NIH to provide cost analysis.

Chairman MAGNUSON. We are all concerned about waste and mismanagement. NIH has received its share of criticism on that. We want to know what you are doing.

Dr. FREDRICKSON. We are vigorously following up any suggestion or lead about waste and mismanagement, sir, and we are very conscious of the need to maintain what I think is a good reputation.

5-PERCENT REDUCTION

Chairman MAGNUSON. Now, if the committee were to recommend a 5-percent cutback in NIH, what areas would you recommend we reduce?

We will ask each director that question separately.

Dr. FREDRICKSON. All right, sir.

I think the best answer that I can give you will require another question, that is, what would be the long-range congressional intent?

Would this be a permanent reduction in the capacity of the system, or would it be a one-time cut?

We would treat certain long-range investments, like training and administrative mechanisms, differently depending on the answer.

However, I can tell you the basic rules that we would follow if we were to receive a 5-percent reduction.

First of all, we would protect research projects, the investigator-initiated extramural research grants.

We would maintain competing awards at the budget level currently in the President's budget. That is, we would keep the same amount of dollars available to fund a certain number of competing grants, because we must be able to take on new research and the competing renewal grants which result from the ending of noncompeting awards, approximately one-third of our extramural grants.

Chairman MAGNUSON. Wait a minute. Do I understand about one-third of your grants——

Dr. FREDRICKSON. Terminate each year.

Chairman MAGNUSON. Terminate after 3 years.

So about one-third. So you would look at those.

Dr. FREDRICKSON. We would want to protect the ability to fund a certain number of those competing renewals.

Chairman MAGNUSON. But if you look at them, there might be something you have to let go.

Dr. FREDRICKSON. We would look at all of them.

Chairman MAGNUSON. At least you've got one-third of the grants to look at?

Dr. FREDRICKSON. That is correct, approximately. And we must preserve our purchasing power, in order to allow those researchers to compete again. Otherwise, they would be frozen out.

We would also make sure that intramural research shared some of the dollar reductions that would be required, like the extramural programs.

The intramural program uses most of its funds to pay salaries. Since you can't easily reduce in this area, we would have to make our reductions primarily in other objects, like supplies. This would affect our ability to do research.

We would have to reduce training too Mr. Chairman. And, as I indicated in my initial response to your question, how much we reduce training would depend upon whether we took the 5-percent reduction, on top of the reduction in trainees to fund the increase in stipends. Altogether, it might mean a 15-percent decrease in the number of our trainees.

If we were to maintain this reduction over a long period of time, we would have to reduce training more than we would if this were a one-time cut. But we would certainly have to reduce the number of trainees, to make sensible adjustment for our priorities.

We would have to protect certain areas, preferentially. We would not reduce the National Library of Medicine the full 5 percent, because it is a service-oriented resource, upon which the whole Nation depends.

We couldn't reduce the clinical center by the full 5 percent, because that might reduce the funding to the point that it would be inoperable.

We would have to take reductions in administrative costs, without any question.

It is difficult Mr. Chairman, because in order to reduce by 5 percent, we would have to renegotiate and reduce all those grants that are now being funded, some 14,000 grants.

We would have to renegotiate in order to protect that competing amount that I said was our highest priority. You can't do that without administrators. In fact, coping with the burden of a severe budget reduction would increase our administrative burden at first, but we would also have to reduce those administrative costs.

It is clear that contracts and centers, and certain special programs would suffer the most under these proposals to cope with such a reduction.

Chairman MAGNUSON. Go ahead.

Dr. FREDRICKSON. Mr. Chairman, I must also say that, in giving you a general answer, it might be necessary for us to request from you some reprograming authority, under very careful controls, for the Director of NIH, I don't think that we could cope with the 15-percent reduction in the total capacity of the national system which would occur if 5 percent were added to the 10 percent due to inflation, unless we had the authority to balance out some of these decisions by moving funds between appropriations.

Chairman MAGNUSON. Of course, that is based, or would be based upon an instruction that the Director cut 5 percent overall, and you would have to make the cuts.

Supposing the committee said that we will mark up all the Institutes, and now each Institute has got to take a 5 percent cut.

Dr. FREDRICKSON. I think that if you are determined to make a 5 percent cut, Mr. Chairman, that is not the best way to do it.

Chairman MAGNUSON. I'm not suggesting that this is the best way. But I'm asking what the effect would be if that happens?

Dr. FREDRICKSON. If that happens, you can be assured that——

Chairman MAGNUSON. Everyone would have to take a cut.

Dr. FREDRICKSON. That is correct. The Institutes will do the best they can with what they have left, and they will still have a research capability.

They would have to deal with that individually. I would have some opinions that I'm sure might differ with theirs in certain areas.

RESEARCH CENTERS

Chairman MAGNUSON. Now, there are a lot of different centers you have. You have over 500, don't you?

Dr. FREDRICKSON. Yes, we have many, sir.

Chairman MAGNUSON. Do you think that the centers program is going to be expanded in the future?

Dr. FREDRICKSON. Well, I think——

Chairman MAGNUSON. You suggest that with regard to intramural research at NIH——

Dr. FREDRICKSON. We would not expand intramural research at the expense of research centers. We would have to look at the balance between the two.

Also as I said, we would first protect investigator-initiated research projects. We think that is the best national investment in times of extreme austerity. That means that centers, along with contract research would have to suffer.

Senator SCHWEIKER. I wonder, Mr. Chairman, if I may ask a question on centers.

Do you have a breakdown of those centers? And if not, will you provide that for the record?

Dr. FREDRICKSON. We will provide you an analysis of that.

[The information follows:]

ANALYSIS OF NIH CENTERS PROGRAM

In response to the request for information on the NIH Research Centers Program, we are happy to provide the following analysis. All research centers programs supported by the NIH are authorized under Title III, Part A, Section 301 of the Public Health Service Act. Specific legislative mandates have been identified.

NATIONAL INSTITUTES OF HEALTH

Analysis of Research Centers Program
(dollars in thousands)

Name of Center	1979 Estimate No.	1979 Estimate Amount	1980 Estimate No.	1980 Estimate Amount	Mandate
National Cancer Institute					
Cancer Research Centers	74	$63,294	74	$63,294	National Cancer Act of 1971, P.L. 92-218, Section 408(a) and (b) Amended by Community Mental Health Centers Extension Act of 1978, P.L. 95-622, Section 406(a) and (b)
TOTAL, NCI.....	74	63,294	74	63,294	
National Heart, Lung, and Blood Institute					
National Research and Demonstration Centers for Heart, Blood Vessel, Lung, and Blood Diseases and Blood Resources.....	3	6,398	3	6,296	National Heart, Blood Vessel, Lung, and Blood Act of 1972, P.L. 92-423. Section 415(a) and (b) Amended by Health Research and Health Services Amendments of 1976, P.L.94-278 Section 415(a) and (b) Amended by Biomedical Research Extension Act of 1977, P.L. 95-83, Section 415(a)(1)(A); (a)(1)(c); and (b) Amended by Biomedical Research Training Amendments of 1978, P.L. 59-622 Section 415 (a)(2)(E)

Analysis of Research Centers Program - (cont.)
(dollars in thousands)

Name of Center	1979 Estimate No.	1979 Estimate Amount	1980 Estimate No.	1980 Estimate Amount	Mandate
NHLBI (cont.)					
Comprehensive Sickle Cell Centers.....	10	$10,950	10	$11,312	National Sickle Cell Anemia Control Act, P.L. 92-294, Section 1102 National Sickle Cell Anemia, Cooley's Anemia, Tay-Sachs, and Genetics Disease Act, P.L. 94-278, Section 1102 Genetic Diseases, Hemophilia Programs, and Sudden Infant Death Syndrome Act, P.L. 95-38, Section 1102
Specialized Centers of Research (SCOR).....	46	43,330	48	47,923	Departments of Labor, and Health, Education, and Welfare, and Related Agencies Appropriation Bill, 1971. Senate Report No. 91-1335, pg. 37: "The Committee has heard considerable testimony for a number of years, both from the Institute and from public witnesses, on the desirability of establishing a number of cardiovascular research centers... The Committee therefore recommends an increase of $8 million which will make it possible to establish additional centers... "

Analysis of Research Centers Program - (cont.)
(dollars in thousands)

Name of Center	1979 Estimate No.	1979 Estimate Amount	1980 Estimate No.	1980 Estimate Amount	Mandate
NHLBI (cont.)					
Specialized Centers of Research (cont.)					Departments of Labor, and Health, Educatin and Welfare, and Related Agencies Appropriations Bill, 1973 Senate Report No. 92-894, pg. 46: "To stimulate research on lung diseases, the Institute established 11 Specialized Centers of Research in 1971 and plans to increase this network to 17 in 1972.. ... There is an urgent need for resources where respiratory diseases in age groups from infancy to early adulthood can be studied by a multidisciplinary group using the most sophisticated techniques. The Committee, therefore recommends that $5 million of the increase in this appropriation be used for a new program in pediatric pulmonary centers.... "
TOTAL, NHLBI.....	59	60,678	61	65,531	
National Institute of Dental Research					
Dental Research Institutes.....	5	7,476	5	7,476	Departments of Labor, and Health, Education and Welfare, and Related Agencies Appropriation Bill, 1967. House Report No. 1464, pg.25: "... The Committee believes that the

Analysis of Research Centers Program - (cont.)
(dollars in thousands)

Name of Center	1979 Estimate		1980 Estimate		Mandate
NIDR (cont.)	No.	Amount	No.	Amount	
Dental Research Institutes (cont.)					creation of a limited number of dental research institutes is probably the most effective approach and has therefore included $3 million in the appropriation of the NIDR ... " Departments of Labor, and Health, Education, and Welfare Appropriations Bill, 1967. Senate Report No. 1631, pg. 47-48. "The committee therefore endorses the action of the House in adding $3 million to the appropriation to establish six university-based dental Institutes."
Periodontal Research Centers..	4	1,702	4	1,702	Departments of Labor, and Health, Education, and Welfare Appropriations Bill, 1978. House Report No. 95-381, pg. 30. "The Committee has learned that the Institute has taken a major step to enlarge its clinical investigations of periodontal disease through the proposed establishment of a limited number of specialized clinical research centers."
TOTAL, NIDR.....	9	9,178	9	9,178	

Analysis of Research Centers Programs - (cont.)
(dollars in thousands)

Name of Center	1979 Estimate No.	1979 Estimate Amount	1980 Estimate No.	1980 Estimate Amount	Mandate
National Institute of Arthritis, Metabolism, and Digestive Diseases					
Multidisciplinary Centers.....	11	$6,560	11	$6,954	None
Multipurpose Arthritis Centers.	26	8,100	26	8,586	National Arthritis Act of 1974, P.L.93-640 Section 4.
Diabetes Research & Training Centers.....	8	8,190	8	8,681	National Diabetes Mellitus Research & Training Act, P.L. 93-354, Section 5.
Kidney Specialized Centers of Research (SCOR).....	5	2,268	5	2,404	Departments of Labor, and Health, Education, and Welfare Appropriations Bill, 1977. Senate Report No. 94-997, pg. 51. "Specialized Centers of Research (SCOR) have proved to be a highly successful approach to research on other diseases, and the Committee is interested in establishing SCOR centers for kidney and genitourinary diseases as well... ... Because of the Committee's strong interest and support for prevention and treatment programs, the Committee has allowed up to $3,500,000 for the development of these centers."
TOTAL, NIAMDD.....	50	25,118	50	26,625	

Analysis of Research Centers Programs - (cont.)
(dollars in thousands)

Name of Center	1979 Estimate No.	1979 Estimate Amount	1980 Estimate No.	1980 Estimate Amount	Mandate
National Institute of Neurological & Communicative Disorders & Stroke					
Research Grants Supported					
Stroke.....	14	6,904	14	6,904	Departments of Labor, and Health, Education, and Welfare and Related Agencies Supplemental Appropriations Bill, 1966. Senate Report No. 680, pg. 15. " The Neurology Institute has already established three clinical research centers devoted to the study of stroke patients... It is highly desirable that similar cerebrovascular clinical research centers be established throughout the country. The Institute has plans for establishing 25 stroke research centers in various parts of the country during the next few years. The recommended appropriation includes $1,500,000 which will make it possible to establish six such centers during fiscal year 1966."

Analysis of Research Centers Programs - (cont.)
(dollars in thousands)

Name of Center	1979 Estimate No.	1979 Estimate Amount	1980 Estimate No.	1980 Estimate Amount	Mandate
NINCDS (cont.)					
Stroke (cont.)					Departments of Labor, and Health, Education, and Welfare Appropriations Bill, 1971. Senate Report No. 91-1335, p. 41. "The Institute has established 17 clinical stroke centers as prototypes of what can be done in research, training and patient care. The Committee believes that the time is ripe to expand this effort and therefore directs that $12 million of the increase be used to develop ten additional centers, expand the activities of the existing centers, and support training programs in the stroke field."
Head Injury.....	6	$2,864	6	$2,864	Departments of Labor, and Health, Education, and Welfare and Related Agencies Appropriation Bill, 1967. Senate Report No. 1631, pg.53. "A substantial research and training program on accidental head injuries and consequent brain damage should be launched without delay. The committee has included $1.5 million in the appropriation for this purpose."

Name of Center	1979 Estimate No.	1979 Estimate Amount	1980 Estimate No.	1980 Estimate Amount	Mandate
NINCDS (cont.)					
Head Injury (cont.)					Departments of Labor, and Health, Education, and Welfare and Related Agencies Appropriations Bill, 1968. Senate Report No. 469, pg. 41: "... The Institute has created a Section on Head Injury and has made several planning grants for the establishment of specific clinical research centers for work on the cause, prevention and treatment of accidental brain damage. ... In order to expand this new program to an effective operating level, an additional $2 million is provided in this appropriation."
Spinal Cord.....	5	2,622	5	2,622	Departments of Labor, and Health, Education, and Welfare and Related Agencies Appropriations Bill, 1971. Senate Report No. 91-1335, pg.41. "A Spinal Cord Injury Center could integrate the best resources of a clinical research center and a community emergency facility... "The Institute has recently launched two small pilot centers but the Committee believes that six additional pilot centers should be established as quickly as possible and has

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Name of Center	1979 Estimate		1980 Estimate		Mandate
NINCDS (cont.)	No.	Amount	No.	Amount	
Spinal Cord (cont.)					included $600,000 in the bill for this purpose. It is expected that from these eight pilot projects it will be possible to establish four fully-fledged centers."
Demyelinating/Multiple Sclerosis.....	8	4,123	8	4,123	Departments of Labor, and Health, Education, and Welfare, and Related Agencies Appropriations Bill, 1973. Senate Report No. 92-894, pg.53: "Last year this Committee suggested that the Institute explore the feasibility of establishing geographically disbursed multiple sclerosis centers. The Committee is pleased to see that one West Coast center is now operational and that an East Coast center is expected to be underway soon. Several more such centers should be created as soon as possible." Departments of Labor, and Health, Education, and Welfare, and Related Agencies Appropriations Bill, 1968. Senate Report No. 469, pg. 41: "The bill also includes an increase of $1.5 million for the extension of research on degenerative diseases. Of

Analysis of Research Centers Programs - (cont.)
(dollars in thousands)

Name of Center	1979 Estimate		1980 Estimate		Mandate
NINCDS (cont.)	No.	Amount	No.	Amount	
Demyelinating/Multiple Sclerosis (cont.)					pg. 41 cont. this amount, $500,000 is for work on the effect of drugs on degenerative diseases and $1 million is for research on multiple sclerosis including the establishment of a multiple sclerosis center which has long been in the planning stage..."
Disorders of Aging.....	4	$2,257	4	$2,257	None
Epilepsy/Paroxysmal.....	6	2,346	6	2,346	Departments of Labor, and Health, Education, and Welfare, and Related Agencies Appropriations Bill, 1973. House Report No. 92-1118, pg. 31: "It will be expected that part of the increase over the budget request will be used for Institute-supported epilepsy centers."
Neuromuscular.....	3	1,924	3	1,924	None
Hearing.....	3	1,567	3	1,567	Departments of Labor, and Health, Education, and Welfare, and Related Agencies Appropriations Bill, 1972. Senate Report No. 92-316, pg. 48: "Additional clinical research centers and out-patient clinical units must be established to provide for
Ear/Vestibular System.....	5	2,567	5	2,567	
Speech/Language.....	4	922	4	922	

Analysis of Research Centers Programs - (cont.)
(dollars in thousands)

Name of Center	1979 Estimate No.	1979 Estimate Amount	1980 Estimate No.	1980 Estimate Amount	Mandate
NINCDS (cont.)					pg. 48 cont.
Hearing Ear/Vestibular System Speech/Language cont.					comprehensive research programs on on diagnosis and treatment of communicative disorders."
Auditory Prosthesis.....	1	$204	1	$204	None
Total, Research Grants Supported	59	28,300	59	28,300	
NINCDS					
R&D Contracts Supported					
Comprehensive Epilepsy Centers..	5	6,120	5	6,120	None
Comprehensive Stroke Centers....	3	1,800	3	1,500	None
Exploratory Trauma Centers.....	6	284	--	--	None
Comprehensive Trauma Centers....	--	--	2	1,000	None
Total, R&D Contracts Supported..	14	8,204	10	8,620	
TOTAL, NINCDS.....	73	36,504	69	36,920	

Analysis of Research Centers Programs - (cont.)
(dollars in thousands)

Name of Center	1979 Estimate		1980 Estimate		Mandate
National Institute of Allergy & Infectious Diseases	No.	Amount	No.	Amount	
Asthma and Allergic Diseases Centers (AADC).....	14	$1,834	14	$1,878	Departments of Labor, and Health, Education, and Welfare and Related Agencies Appropriations Bill, 1971. Senate Report No. 91-1335, pg. 42: "The Institute proposes to establish a small number of clinical allergy research centers.... The Committee believes that the launching of these units is a necessary step in translating the results at the laboratory bench into practical application..., and must not be delayed."
Centers for Research in Immunologic Diseases (CIRID).....	4	1,181	4	1,252	Departments of Labor, and Health, Education, and Welfare and Related Agencies Appropriations Bill, 1979. House Report No. 95-1248, pg. 35: "The Committee wishes to reiterate its interest in the establishment of a program for interdisciplinary research in immunology consisting of at least three pilot centers."
International Centers for Medical Research.....	4	2,328	--	--	International Health Research Act of 1960, P.L. 86-610, Section 2.

Analysis of Research Centers Programs - (cont.)
(dollars in thousands)

Name of Center	1979 Estimate		1980 Estimate		Mandate
NIAID (cont.)	No.	Amount	No.	Amount	
International Collaboration* in Infectious Disease Research (ICIDR).....	2	$800	3	$1,332	None
TOTAL, NIAID.....	24	6,143	21	4,462	
National Institute of General Medical Sciences					
Pharmacology-Toxicology Research Centers.....	7	4,300	7	4,500	Departments of Labor, and Health, Education, and Welfare and Related Agencies Appropriations Bill, 1967. Senate Report No. 1631, pg. 37: "The Committee has added $1,000,000 to the appropriation for NIGMS to facilitate the establishment of pharmacology-toxicology research centers for which inadequate funds are included in the budget estimates."
Biomedical Engineering Research Centers.....	4	2,000	4	2,500	Departments of Labor, and Health, Education, and Welfare and Related Agencies Appropriations Bill, 1974. Senate Report No. 93-414, pg. 53:

* The ICIDR program actually consists of R-21s and POls. Although originally conceived as a centers program and reported as such in the 1980 President's Budget, it will in the future appear in the research projects line.

Analysis of Research Centers Programs - (cont.)
(dollars in thousands)

Name of Center	1979 Estimate		1980 Estimate		Mandate
NIGMS (cont.)	No.	Amount	No.	Amount	
Biomedical Engineering Research Centers (cont.)					pg. 53: "The committee believes that a portion of the Congressional increase should be used for the establishment of biomedical engineering centers which would, among other activities, generate new and improved instruments and devices for the detection, diagnosis, and treatment of disease..."
Diagnostic Radiology Research Centers.....	1	$600	1	$600	None
Anesthesiology Research Centers	3	2,600	3	2,600	Departments of Labor, and Health, Education, and Welfare, and Related Agencies Appropriations Bill, 1967. Senate Report No. 1631, pg. 37: "The Committee also recommends $500,000 so that the Institute can establish a center for research in anesthesiology."
Trauma and Burn Research Centers.....	12	4,400	10	3,700	Departments of Labor, and Health, Education, and Welfare, and Related Agencies Appropriations Bill, 1974. House Report No. 93-305, pg. 38:

Analysis of Research Centers Programs - (cont.)
(dollars in thousands)

Name of Center	1979 Estimate		1980 Estimate		Mandate
NIGMS (cont.)	No.	Amount	No.	Amount	
Trauma and Burn Research Centers (cont.)					pg. 38: "Some of the additional funds should also be used to increase the number of trauma centers on accidental injury."
Genetic Research Centers.....	9	$5,200	8	$4,700	Departments of Labor, and Health, Education, and Welfare, and Related Agencies Appropriations Bill, 1972. Senate Report No. 92-316, pg. 52: "The Committee recommends that the Institute move ahead as rapidly as possible with its plans for developing ten or twelve large scale projects and genetic centers to be situated at major medical schools in various parts of the country."
Molecular Pathology Research Centers.....	3	1,529	2	1,159	Departments of Labor, and Health, Education, and Welfare, and Related Agencies Appropriations Bill, 1974. Senate Report No. 93-414, pg. 52-53: "The Committee believes that a significant portion of the Congressional increase should be devoted to this program, including the initiation of the molecular pathology centers."
TOTAL, NIGMS.....	39	20,629	35	19,759	

Analysis of Research Centers Programs - (cont.)
(dollars in thousands)

Name of Center	1979 Estimate		1980 Estimate		Mandate
National Institute of Child Health & Human Development	No.	Amount	No.	Amount	
Mental Retardation Research Centers.....	12	$7,334	12	$7,334	Mental Retardation Facilities and Community Mental Health Centers Construction Act of 1963, P.L. 88-164, Title I, Section 101.
Major Research Programs.....	10	6,063	11	6,572	Departments of Labor, and Health, Education, and Welfare, and Related Agencies Appropriations Bill, 1976. House Report No. 94-311, pg. 38: "The Committee believes that the Institute must move ahead with its plan to develop 12 major research programs..."
Population Research Centers....	27	9,090	32	10,590	None
TOTAL, NICHD.....	49	22,507	55	24,496	
National Eye Institute					
Core Center Grants.....	22	4,149	23	4,197	Departments of Labor, and Health, Education, and Welfare, and Related Agencies Appropriations Bill, 1976. House Report No. 94-311, pg. 42: "The Committee believes NEI should explore the awarding of core center

Analysis of Research Centers Programs - (cont.)
(dollars in thousands)

Name of Center	1979 Estimate No.	1979 Estimate Amount	1980 Estimate No.	1980 Estimate Amount	Mandate
NEI (cont.)					
Core Center Grants (cont.)					pg. 42 cont. grants to institutes of high research productivity potential. Some centers are currently overburdened with routine care because of the need to generate funds to support research activities. These core center grants will provide researchers with expanded support for creative activity in furtherance of the new vision research program plan." Departments of Labor, and Health, Education, and Welfare, and Related Agencies Appropriations Bill, 1975. Senate Report No. 93-1146, pg. 64: "The additional funds included for center grants should be awarded on a merit basis as determined by the peer review system. In order to insure the maximum quality of these centers, the core center grant mechanism should be utilized to the greatest extent possible."
Specialized Clinical Research Center Grants.....	7	1,561	10	1,593	None
TOTAL, NEI.....	29	5,710	33	5,790	

Analysis of Research Centers Programs - (cont.)
(dollars in thousands)

Name of Center	1979 Estimate		1980 Estimate		Mandate
	No.	Amount	No.	Amount	
National Institute of Environmental Health Sciences					
Environmental Health Sciences Centers.....	9	$8,907	9	$9,362	None
Marine and Freshwater Biomedical Centers.....	5	660	6	835	None
TOTAL, NIEHS.....	14	9,567	15	10,197	
National Institute on Aging					
Core Center Grants.....	1	318	1	318	None
Division of Research Resources					
Clinical Research Centers....	74	51,614	68	51,520	None
Biotechnology Research Centers.....	38	11,447	36	11,703	None
Primate Research Centers.....	7	15,242	7	15,242	None
TOTAL, DRR.....	119	78,303	111	78,465	

NEW GOVERNMENT ACT

Chairman MAGNUSON. I'm all through, and I call upon you to ask questions.

There is one thing that I wanted to ask you about, Doctor. When the Secretary was before us yesterday, he raised the question of possible adverse effects from the new Government act. Are you familiar with that?

Dr. FREDRICKSON. Yes, I am.

Chairman MAGNUSON. And what effect it might have on HEW and NIH.

I don't think that Congress intended to do what they are arguing about with regard to the interpretation. It is going to be a serious matter for you people, and the National Science Foundation and organizations of that kind are involved, too.

Do you have any comment to make on that?

Dr. FREDRICKSON. We are greatly concerned about that.

Chairman MAGNUSON. I mean coming and going. This can work both ways. Not only the people in the Government going out, but getting people for special jobs in the Government for you people.

Dr. FREDRICKSON. If the law were to stand as it is now, without any amendment or effective gloss of interpretation, I think you could expect to see a marked decline in staffing immediately in some of the key positions at NIH, and an extraordinarily difficult time in replacing those people.

Chairman MAGNUSON. Well, the administration is quite concerned with it, too, or so the Secretary said on Monday.

We will see if we can't work something out. I don't think that Congress intended to go this far dealing with the intermingling of sciences in the field of education, and so forth, but it is something that is a serious matter.

Dr. FREDRICKSON. At the moment, it is a serious matter.

Chairman MAGNUSON. Just one more question.

PAPERWORK

What are you doing about paperwork?

Dr. FREDRICKSON. Well, we have shortened the grant application.

Chairman MAGNUSON. Your people complain, the scientists complain, and everybody is complaining about paperwork.

Dr. FREDRICKSON. The scientists are complaining, and we have analyzed their problems with regard to paperwork. We are now doing something about their grant applications, which I think is a very important first step.

We are also looking at our requirements for reporting from scientists, the institutional review boards, and there are many other regulations that affect us.

The recombinant DNA guidelines are necessary, but they are a real imposition on scientists. This is true for many of the regulations, and we expect a greater accountability from everyone, including ourselves.

We are also attempting, however, to analyze the reports that we make. I now want on the cover of every report what it costs, because we all need to think what it requires to generate an annual report. We want you to have those figures, too, Mr. Chair-

man, because they may be useful to you in making some decisions about the necessity of an annual report, as opposed for instance, to a biannual one.

We want to keep up with the congressional demands that the administration requests, but we want to be conscious of the costs as well.

We understand the paper problem, and we are constantly trying to sample both the research community and our administration to see if we can minimize the amount of extra paperwork which is a burden to all of us.

Chairman MAGNUSON. This is off the record.

[Discussion off the record.]

Chairman MAGNUSON. OK. The Senator from Pennsylvania.

Senator SCHWEIKER. Thank you, Mr. Chairman.

RESEARCH CENTERS

Following up, Dr. Fredrickson, in analyzing the budget, the way I read your budget, the centers increase by $7 million, but research projects go down by $6 million.

That would seem to somewhat contradict the priority list that you just outlined to us as to what to do in the event of a cut.

Dr. FREDRICKSON. Senator Schweiker, are you reading from the mechanism summary?

That is correct.

Senator SCHWEIKER. Yes. It just seems contrary to what you said you would do if you have to cut.

Dr. FREDRICKSON. One of the reasons that the centers line is so high is that we have a number of mandates that we are attempting to satisfy with regard to research centers.

Senator SCHWEIKER. I would suggest that in the analysis you give me include the mandate.

Dr. FREDRICKSON. Yes. We would be happy to do that.

Senator SCHWEIKER. OK.

Now, we talked about a 5-percent cut, which I assume the chairman means is a reduction of 5 percent from expenditures presently being used.

EFFECTS OF INFLATION

My question to you is, if you have a no-growth budget, or zero increase over last year, in terms of biomedical research, which basically the President's budget is for NIH, what kind of de facto cut does that amount to based on inflation of biomedical research costs?

Dr. FREDRICKSON. I would guess the reduction in purchasing power will be about 8 percent.

Senator SCHWEIKER. So a no-growth budget means that you are going to have to find something to cut 8 percent?

Dr. FREDRICKSON. That is true.

Senator SCHWEIKER. Would an analysis of what you gave us of what a 5-percent real cut meant as opposed to an 8-percent de facto cut, would your analysis be similar as to where your spending priorities occur, or not?

Dr. FREDRICKSON. Yes, it would be similar.

As I mentioned to the chairman, I would have to worry about the effect on the total system, so a 5-percent cut added to the inflation factor would be about a 15-percent reduction in the capacity to support that system for 1 year.

ADMINISTRATIVE LIMITATIONS

Senator SCHWEIKER. What effect have the new limitations on consultants, staff travel, and other scientific support functions had on the intramural programs and investigators at NIH?

Dr. FREDRICKSON. The effect is not serious at the present time. I think that we are awaiting clarification of whether consultants include the expert appointments, which are very crucial to us. A serious effect has not yet occurred.

YOUNG INVESTIGATORS

Senator SCHWEIKER. What is the NIH policy on research projects support for young investigators?

Dr. FREDRICKSON. We have a number of programs that have been developed over the past several years. Specifically, the young investigator award itself, which has been established for the past few years, is designed to support or offer opportunity for support for a person entering the system for the first time.

We have taken cognizance of this particular problem. We are countering the difficulty in getting into the system by making some preferential opportunities for such support.

We can give you further illustration of that in the record if you wish.

[The information follows:]

YOUNG INVESTIGATORS

We have a number of programs that have been developed over the past several years. Specifically, the young or new investigator award itself is designed to support or offer opportunity for support for a person entering the system or a new field for the first time.

The following table summarizes the history of the new investigator grant application since its beginning in 1971.

NEW INVESTIGATOR (R23) APPLICATIONS FUNDED 1971–78

Fiscal year	Number	Thousands
1971	32	$322
1972	7	62
1973	18	154
1974	70	2,074
1975	78	1,642
1976	67	1,963
1977	105	3,309
1978	199	7,168

We are pleased with the results of this initiative and plan to maintain our efforts.

Senator SCHWEIKER. Fine, all right.

RADIATION

I note from the paper this morning Secretary Califano has called for expanding Government studies to determine the dangers of exposure to low-level nuclear radiation. It is thought that the incidence of leukemia produced by low radiation levels may be higher than scientists thought.

My question to you is: Can you tell us about the seriousness of this problem, and what NIH will be doing to deal with it?

Dr. FREDRICKSON. NIH has received a special mandate from the Secretary to do several things, Mr. Schweiker.

One of those is to set in place a program to study the biological effects of ionizing radiation. At the beginning this program will probably be located primarily in the National Cancer Institute, and it will include both biological and epidemiological research.

The second mandate we have is to take responsibility for all of the research within the HEW on the human effects of ionizing radiation. Part of our responsibility will be to develop awareness, and to sponsor an analysis of all research in this area, so that we may derive some more coordinated idea of the patterns of research on biological effects of low-level radiation.

There are so many agencies now sponsoring so many kinds of research that there is some element of chaos, that we believe it is extremely important to try to bring some order into our understanding.

Senator SCHWEIKER. What about the seriousness of the problem?

Dr. FREDRICKSON. I think the problem is serious, both from a health standpoint, and from the standpoint of enormous public anxiety and uncertainty.

There are a number of people who do not know whether they really are at particular hazard, because of their exposure to radiation. We really don't have answers to many questions raised about today's standards for exposure to radiation.

It is very difficult to get a complete and satisfactory answer to these questions.

The data are limited, and it is clear that it will be some time before we can allay the anxieties that we all have about what radiation exposure really means, in terms of the weapons tests in the past, or the development of nuclear reactors in the future. There are some enormous health implications.

PROGRAM BREAKTHROUGHS

Senator SCHWEIKER. I recently saw an article indicating that the work of the National Heart, Lung, and Blood Institute contributed significantly, or may have, to a dramatic decline in deaths from strokes.

That obviously suggests a case where the taxpayers may be getting something very specific and very direct and very immediate for their investment.

My question to you is: How do you build that kind of a return into our approach on NIH funding, in terms of priorities? Just like the 15-percent cutback we were talking about.

HEW does something like that, that obviously occurred to me as being very cost effective, and probably bringing much saving in terms of ultimate cost impact on our health system.

How do we prioritize that into our selection process, and are we doing that now?

Dr. FREDERICKSON. That is probably the key question when you direct a research enterprise such as this. What you are referring to, can justifiably be attributed in part to that institute and its scientists, but it didn't just begin yesterday.

What we are now seeing is the fruition of 30 years or more of research, in understanding blood pressure, and development of ways to control it, and its consequences.

In a field such as cardiovascular disease, the effort is much more matured in terms of its development than other fields, and we are beginning to see the payoffs in dramatic terms.

The way that we must be stewards for our research responsibility basically stands upon several principles.

One, we must keep a vigorous science base, because there are many things that we will learn about biology which are not yet even predictable. Certainly we can't program or schedule accurately the development from basic research the interventions that will treat, diagnose, and prevent.

The second principle is to make sure that of the vigorous activity which we have discussed today, there continues to be selective application. So that when we see an opportunity, we drive it efficiently and effectively toward practical development. Then we must see that it's transferred to the practitioner and the public.

The Heart, Lung, and Blood Institute has given a good indication of how this activity, technology transfer, had gained expression and had some effect in reducing mortality and morbidity.

INSTITUTE PRIORITIES

Senator SCHWEIKER. Do we have a method of rating that gives a work like this a high priority under our point system or whatever? It seems to me that is a pretty key question.

Dr. FREDRICKSON. Yes, we do.

Senator SCHWEIKER. My question is: Is this a uniform priority, or what kind of priority does this have in our peer review process?

Dr. FREDRICKSON. It lies within a system of priorities which are determined in this instance largely at the level of the advisory council; that is, the institutes discuss with their councils how they want to spread their resources, knowing they must protect the investigator-initiated research activities.

Making choices about what can be developed into real interventions, in order to have a real effect on health, is much easier than determining the direction of certain nuances in biology.

If the councils can establish what the problems are, then they can decide how much they want to spread their investment to accomplish these things.

The institutes have become extremely good in the past 2 years in making these programmatic decisions. We have begun using a programmatic system so that we can make these selections much more effectively than we could in the past.

We have to weigh the benefits and opportunities. We are constantly weighing technical opportunity, the likelihood of getting an answer, against the importance of that answer. I think that is our whole business.

Your question is a very good one. It is something we deal with all the time, and in my review annually with the individual Institutes, we ask the questions: what is it that you can do tomorrow; what is it that you can do today; which is more important; where will you put your money if you get some increase; where will you reduce if you get a decrease.

We have gone through this intensive review for the last 3 or 4 years. You can ask that question of the director of any Institute here and you will get a sense of what their priorities are.

EMPLOYMENT CEILINGS

Senator SCHWEIKER. The staff positions for the research grants are a component of your office. This staff has remained essentially constant for the past few years, while the grant review workload has probably increased, and probably doubled.

Is this a significant problem? And what happened to the positions we authorized for NIH in fiscal 1979?

Dr. FREDRICKSON. This is a problem, Mr. Schweiker, a real problem. We have taken cognizance of the authorization of those positions, and we are going to provide selectively a few more positions to the division of research grants, as best we can.

We are, however, under a reduction in ceiling that will not allow us to increase that particular division by the 40-some positions which were in our appropriation last year.

Senator SCHWEIKER. We had specifically included full-time positions; and we have had an ongoing misunderstanding of this.

I think we mandated the positions into law.

Chairman MAGNUSON. Yes, I think we mandated that.

Senator SCHWEIKER. Exactly.

Now, where do we stand on those?

Mr. FORBUSH. We have operated within the limits of the President's employment ceiling. Although the positions are mandated in the law, it is not legally necessary to have them filled.

Senator SCHWEIKER. We wrote this very specifically, so that we would have a remedy if they weren't filled.

Mr. FORBUSH. It is our opinion that the language actually enacted did not actually do that.

Senator SCHWEIKER. How many of the new positions have been filled?

As I read it, I think it is about 200 positions in the Department. This is for the Department, 200 positions in the Department.

Mr. FORBUSH. I think it is a little higher than that. But because of the employment ceiling——

Senator SCHWEIKER. It is higher than that.

Go ahead.

Mr. FORBUSH. Because of our current employment ceiling, I do not think we will be able to fill those positions in 1979.

I think we will do better in 1980 if Congress approves our proposed staffing trade offs. We also have a modest increase in our overall ceiling.

But in 1979, I do not think we will be able to fill very many of the new positions.

The Secretary has assigned a total ceiling to the Public Health Service and they are in turn breaking down their ceiling among their components. The allocation to each NIH Institute may not be complete at this point.

The ceiling we have for the Department for 1979 is about 650 below our actual on-duty staff on September 30, 1978.

Senator SCHWEIKER. Would you give us for the record where we stand on all these positions? I think we will probably come back to inquire of the audit as to whether or not there are some positions open. The language was specifically written so that would not occur.

Mr. FORBUSH. The Comptroller General did give you a recommendation as to how to write the language.

Senator SCHWEIKER. And we took his advice.

Mr. FORBUSH. The appropriation act was not written the way the Comptroller General suggested.

Senator SCHWEIKER. All right. Give us that for the record.

Thank you, Mr. Chairman.

[The information follows:]

HEW GENERAL COUNSEL'S OPINION
ON LANGUAGE

NOV 03 1978

MEMORANDUM

TO : The Secretary
Through: U _____
ES _____

FROM : Richard F. Beattie
Deputy General Counsel

SUBJECT: Implementation of Limitation on Hiring

In connection with the Department's implementation of the limitation on hiring ordered by the President you have asked if the hiring limitation is applicable to the agencies of the Public Health Service for which staffing levels are provided in the Labor/HEW Appropriation Act of FY 1979?

For the reasons set forth below, it is our opinion that the hiring limitation applies to PHS agencies notwithstanding the provisions on staffing levels in the Appropriation Act.

DISCUSSION

In previous years, staffing levels for PHS agencies were established in reports of the Appropriations Committees. Last February, Chairman Magnuson of the Labor/HEW Appropriations Subcommittee asked the Comptroller General whether hiring ceilings imposed by HEW at levels below those authorized by Congress constituted illegal impoundments under the Impoundment Control Act of 1974, 31 U.S.C. 1401-1407. In his letter of April 5, 1978 to Sen. Magnuson, the Comptroller General concluded that the imposition of such ceilings did not violate the Impoundment Control Act. He based his opinion on the fact that the Impoundment Control Act applies only to the "rescission or deferral of budget authority." The term "budget authority" as defined in the Congressional Budget and Impoundment Control Act of 1974 means "authority provided by law to enter into obligations which will result in immediate or future outlays involving Government funds ... " 31 U.S.C. 1302. Thus, the Comptroller General noted that

> "[I]n the case of a lump-sum appropriation for salaries and expenses in which funds are provided for increasing staffing levels, no impoundment would exist notwithstanding that a hiring limitation is imposed so long as all of the budget authority was made available for obligation (such as for salary increases or other additional expenses for which the lump-sum appropriation is available) and the agency intends to use the funds. This result follows as matter of law even though the executive branch may be consciously limiting staffing levels contemplated by the Congress. Under the Impoundment Control Act the critical factor is that the budget authority is made available for obligation and expenditure and not the uses for which it is so made."

The Comptroller General further noted in his letter to Sen. Magnuson that if an appropriation act or other statute "specified staffing levels and the funding was made available therefor in a line item, the imposition of a hiring ceiling might well result in impoundments, assuming that the excess funds expected to be realized by limiting hiring could not be reprogrammed or transferred to other uses." (Emphasis supplied)

The number of authorized positions for each PHS agency is specified in the Labor/HEW Appropriation Act. */ Thus, for example, the appropriation for the National Cancer Institute reads:

> "For carrying out, to the extent not otherwise provided, section 301 of the Public Health Service Act with respect to cancer, $917,000,000, including 2,062 full-time permanent positions."

The staffing levels for the PHS agencies specified in the Appropriation Act are not, however, tied to "budget authority." Therefore, if the total number of authorized positions for each PHS agency are not filled because of the imposition of HEW hiring limitations, the Impoundment Control Act would not be violated so long as the total budget authority (e.g. $917,000,000 for NCI) is made available for obligation and expenditure. As noted above, the Comptroller General stated in his letter to Sen. Magnuson that the imposition of hiring ceilings might result in impoundment if the excess funds expected to be realized by limiting hiring could not be reprogrammed or transferred to other uses. There is nothing in the language of the Appropriation Act which earmarks funds solely for the purpose of financing a particular number of positions in each PHS agency. To the contrary, if hiring limitations are set by HEW at levels below those in the Appropriation Act, the entire amounts appropriated for the PHS agencies would, nonetheless, remain available for obligation and expenditure for authorized purposes. As noted by the Comptroller General, under the Impoundment Control Act, the "critical factor is that the budget authority is made available for obligation and expenditure, not the uses for which it is so made."

The Joint Explanatory Statement of the conferees on the Labor/HEW Appropriation Act includes the following statement under the heading "POSITIONS AUTHORIZED FOR HEALTH AGENCIES":

> The conferees agree that the employment levels identified in the bill are not intended to mandate a specific level of employment. The conferees agree that whenever the Secretary determines that he can achieve program goals and objectives with fewer employees, the Congress should be notified of such action through either a rescission or reprogramming request. (H.Rept. No. 95-1746, p. 16)

Although the statement contemplates that the employment levels identified in the Appropriation Act would not be lowered unless the Secretary determines that he can achieve program goals and objectives with fewer employees, there is nothing in the language of the Appropriation Act which requires such a determination to be made. A "rescission" under the Impoundment Control Act would be inappropriate because, as discussed above, a hiring limitation does not constitute a rescission or impoundment of budget authority.

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*/ As noted above, in past years, employment levels for PHS agencies were specified in the reports of the Appropriations Committees.

In sum, the staffing levels for PHS agencies in the Appropriation Act do not constitute an impediment to the imposition of hiring limitations for those agencies in compliance with the President's directive on limitation on hiring in the executive branch.

NIH Employment

In carrying out his own policy of reducing federal employment as well as to implement Section 311 of the Civil Service Reform Act, the President has assigned HEW a 1979 employment ceiling of 142,989. This ceiling is 655 below our actual employment on September 30, 1978, but it is 2,600 above our actual employment on September 30, 1977, the benchmark date for determining compliance with the provisions of Section 311.

The Secretary allocated 50,165 of the HEW-wide ceiling to the Public Health Service; from that number the Assistant Secretary for Health assigned 11,205 to the Director of the National Institutes of Health as a limit for employment on September 30, 1979. Employment within the National Institutes of Health is shown below; employment ceiling has not yet been assigned to the components:

NIH Employment, 1978-1979

	1978		1979		
Institute	Auth. Pos.	Sept. 30 Employment	Auth. Pos.	Jan. 31 Employment	Current Ceiling
NCI	2,042	1,961	2,062	1,941	
NHLBI	774	770	788	715	
NIDR	284	283	287	272	
NIAMDD	622	630	642	643	
NINCDS	552	546	567	536	
NIAID	636	634	649	636	
NIGMS	170	164	179	158	
NICHHD	386	371	400	373	
NIA	223	227	258	233	
NEI	171	156	181	151	
NIEHS	366	245	405	337	
Research Resources	78	79	80	78	
NLM	495	490	503	482	
J.E. Fogarty I.C.	51	48	51	46	
Office of the Director	4,695	4,642	4,780	4,564	
NIH, Total	11,345	11,346	11,837	11,165	11,205

Chairman MAGNUSON. How many people do you have employed now, total?

Dr. FREDRICKSON. Approximately 11,200 people.

Chairman MAGNUSON. How does that compare with the budget?

Dr. FREDRICKSON. The budgeted position level is 11,840, although our current ceiling from the Department is 11,205.

Chairman MAGNUSON. Does that mean there are 600 that haven't been filled?

Dr. FREDRICKSON. There are always a certain number of positions that are vacant, Mr. Chairman.

Chairman MAGNUSON. Does this budget increase the amount of positions you have?

Mr. SCHWARTZ. The fiscal year 1980 recommendation to the committee is 184 positions under the budgeted position level in fiscal year 1979.

Chairman MAGNUSON. So that the average, like 200 unfilled, or 300, or 100, or whatever, is going to be the same, isn't it, in round figures?

Mr. SCHWARTZ. Yes, sir.

Chairman MAGNUSON. It would be about the same?

Mr. SCHWARTZ. That is correct.

I might remind the committee that we've just gone through a period of about 4 months of a freeze on hiring employees from outside the Department. This was a governmentwide freeze.

So we are below where I would normally expect we would be at this time of the year.

Chairman MAGNUSON. Maybe we should have kept the freeze on.

Dr. FREDRICKSON. I don't think we can stand a freeze indefinitely, Mr. Chairman.

Chairman MAGNUSON. Parkinson's law still works, doesn't it?

Dr. FREDRICKSON. We try to avoid Parkinson's law as best we can.

Chairman MAGNUSON. All right.

NIH APPROPRIATIONS

There has been some suggestion made that NIH is always on a roller coaster in appropriations, up or down.

You made a plea last year, you said if you had your way you would like to not necessarily up a lot of items, or cut a lot of items, but keep some stability in them.

Do you think we have gotten off the roller coaster?

Dr. FREDRICKSON. No. I think we are still on the roller coaster, Mr. Chairman. To a certain extent, science will always be a little bit on the roller coaster.

Chairman MAGNUSON. Oh, yes; but not to the extent I think that it is now.

Dr. FREDRICKSON. I think it would assist us as managers, perhaps you as appropriators, and scientists as the active elements in this program, if it were somewhat more predictable. It is difficult nowadays to be sure what kind of a career choice research is.

Chairman MAGNUSON. Well, it is difficult with your system to evaluate appropriations.

But you feel we made some progress?

Dr. FREDRICKSON. I believe we have made progress in setting our priorities. I think we still need to work together to find some possible way to get a greater constancy in predicting funding levels at least, or to try to keep the stability in certain parts of the system.

Some parts bear instability better than others; the science base, I think, much less so than application.

Chairman MAGNUSON. All right.

QUESTIONS SUBMITTED FOR RESPONSES

If there are no further questions, we thank you very much.

Dr. FREDRICKSON. Thank you, Mr. Chairman.

[The following questions were not asked at the hearing, but were submitted to the Department for response subsequent to the hearing:]

FIVE-YEAR PLAN FOR RESEARCH PRIORITIES

Question: Recently, you held a conference to determine how biomedical needs of the next five years should be prioritized. What were the findings of that conference? Please give some specific examples of why you think that conference was helpful and what you got out of it in terms of recommendations.

Answer: On October 3-4, 1978, DHEW Secretary, Joseph A. Califano, convened a National Conference on Health Research Principles at the National Institutes of Health. The purpose of this Conference was to seek public advice in the development of principles for the Department's health research activities. Once a final set of principles is agreed upon, these will serve to guide the development of a five-year plan and budget for health research activities in the Department. The Conference was not structured to determine how biomedical needs of the next five years should be prioritized; rather, it was intended to provide an overall framework within which priorities could subsequently be developed as this planning initiative moves forward.

A draft set of health research principles, developed by the agencies, was presented to five panels at the Conference for their review and modification. Conference staff subsequently analyzed the panel reports and public testimony and developed a revised set of principles. (Copy of Conference Report furnished Subcommittee.) These were mailed to all Conference participants for additional comment and forwarded to the Institute of Medicine, National Academy of Sciences, for a formal critique. The latter has been received in the last few days and based upon this input, the principles will be revised and finalized. The Conference was quite effective in moving this part of the process forward and served a useful purpose in building a foundation upon which a five-year plan can be developed for the Department's health research activities.

HIGHLIGHTS

Question: In your opinion, Doctor, which programs have proven to be most effective in the past few years, and which areas would you suggest are the most important advances or contributions to biomedical research in this country?

Answer: Two major areas of NIH activities have been highly effective in the past few years - the intramural research program and grant-supported extramural research.

In my opening statement I mentioned the leadership provided by our intramural scientists to the biomedical research community as a whole, and their value as a resource to our staff who deal with the large and effective NIH extramural research program.

I should also mention two special NIH programs, one of which has been widely recognized for its effectiveness - the National High Blood Pressure Education Program - and the other, a new program which has begun to achieve our expectations for it - the Consensus Development Program.

In my opening statement I also mentioned several research advances which I believe have significant potential:

- Recent advances in the use of recombinant DNA techniques offer the possibility of commercial production of scarce biological products such as insulin and growth hormone. Such techniques may eventually help us understand the underlying causes of cancer and to treat effectively the genetic diseases.

- Basic research in receptor sites and the possible application of its findings to the treatment of diabetes and other endocrine diseases.

- The development of systemic antiviral agents. An antiviral drug has been developed and licensed for treatment of certain herpes virus infections, an important beginning in dealing with virus infections, a major cause of sickness and medical care costs.

- The application of positron emission transverse tomography (PETT) as an important new diagnostic tool for brain lesions. This sophisticated instrument will for the first time permit an investigator to monitor the details of metabolism and function in the intact living brain.

DNA ADVISORY COMMITTEE

Question: Could you explain the reasoning behind the shifting of the administrative responsibility for the DNA Advisory Committee from the Director's office at NIH to the Secretary's level.

Answer: The administrative responsibility of the Recombinant DNA Advisory Committee (RAC) has not been changed. It continues to be advisory to the Director of NIH, the Assistant Secretary for Health, and the Secretary of HEW. The question may be in reference to the fact that, until recently, advice to NIH and the Department involving recombinant DNA research essentially followed the traditional NIH model of review by a study section and then a public advisory committee.

At the first level, technical experts organized into review panels seek consensus on issues of scientific merit--judgments on the quality of an idea or hypothesis and the likelihood that it can be tested by experimentation. At the next level, typically represented by the advisory council, a broader array of talents and interests assess the relevance of the research to HEW programs and advise the Department concerning other matters of public policy involved in the proposed project.

Until quite recently, advice to the Department involving recombinant DNA research essentially followed this two-tiered model. The RAC served primarily as an initial review group providing the NIH Director with advice on technical issues in this complex field. Two of its sixteen members were laymen and the rest were scientists with interests focused on, or at least broadly related to, aspects of the use of recombinant DNA technology. Care was taken, even at that time, to ensure representation of differing scientific perspectives on the principal issues.

For the second level review, Dr. Fredrickson used his Advisory Committee to the Director (DAC). In preparing the original NIH

Guidelines for Recombinant DNA Research and in drafting the recent revisions, DAC members provided the broader public perspective.

The new procedures permit the evolution of the Guidelines as we gather new knowledge. This evolution is accomplished through a steady flow of interpretations of existing standards by the Office of Recombinant DNA Activities (ORDA) in consultation with the RAC, and through case-by-case analyses and proposed revisions by the RAC of the containment rules as new information is assimilated. All of this occurs under rules affording opportunity for public comment. Thus, the involvement of the RAC is much more "on-line" in character than the phasic, cyclic nature of more traditional peer review.

The sporadic use of the DAC (or some other citizen group) to provide secondary review no longer seems appropriate to the situation. The redundancy of explanation required to assist a second group, removed in expertise and time from the initial actions of the RAC, would be inefficient--indeed, would lengthen the time of NIH's response to scientists' requests under the Guidelines.

Hence, for purposes of implementation, it was decided to compress the traditional two tiers of review into one. This step was taken in the interests of efficiency and timeliness, in order to stimulate rather than retard scientific knowledge in this important arena. The nature of the new RAC is not without precedent. The Genetic Manipulation Advisory Committee in the United Kingdom is a similar hybrid performing similar functions.

This new procedure was developed to address issues raised by proposed recombinant DNA research and does not foreshadow changes in the two-tiered system of NIH for peer review in its other research programs. While the procedure is experimental, it is believed that the new RAC will advance the safe and successful use of recombinant DNA techniques.

INTERNATIONAL HEALTH LEGISLATION

Question: Legislation has been introduced to reorganize and better coordinate international health programs in the United States. What is your reaction to this legislation?

Answer: Recent legislative proposals, such as the Bill (S. 499) to establish a Foundation for Scientific and Technological Cooperation, reflect an increasing realization of the pressing need to achieve greater coordination of Federal efforts to introduce science and technology in foreign countries. These particular recent proposals appear to be designed to address in general terms the broad range of science, engineering, and technology transfer activities conducted as part of a program of international cooperation, and the language does not specifically address the particular problems, needs, and opportunities in international health. Consequently, we can only agree in principle with the intent of this proposed legislation.

Question: What impact, in your mind, is necessary to more properly coordinate the many international health programs that presently exist?

Answer: The question of what constitutes an appropriate mechanism for the coordination of international health activities has been addressed, in several recent studies. Included among these are:

- The Institute of Medicine Study, "Strengthening U.S. Program to Improve Health of Developing Countries;"

- The Report to the President, "New Directions in International Health (The Borne Report); and

- The DHEW study, "An International Health Policy for the HEW."

The problem of coordination has been examined in these studies from the perspective of both inter-Departmental coordination and coordination within the HEW. As part of a commitment to give greater coherence and importance to international activities throughout HEW, the Secretary has established within his immediate office an Office of International Affairs. In addition, to achieve better coordination of international health activities, the Secretary has established an International Health Policy Board which is chaired by the Deputy Assistant Secretary for International Health and is comprised of the PHS Agency Heads and Heads of appropriate OASH and OS staff offices. The Board will be an important mechanism for considering policy issues in international health, reviewing budget recommendations, and coordinating program plans.

Question: Do you feel that the Fogarty Center should remain under the NIH jurisdiction?

Answer: Yes! The FIC serves an important function by providing a central coordinating and integrating focus for the international activities of the categorical Institutes of the NIH. The FIC is an integral part of the NIH and we firmly believe that this relationship should be maintained and strengthened. This view stems from the perceived need to provide a stable environment in which a close working relationship is maintained between the international component of biomedical and behavioral research and the action-oriented categorical Institutes through which the goals of international programs may be realized. We believe, therefore, that the FIC should continue, within the existing framework, to (1)serve as the principal source of advice to the Director, NIH, on all matters related to international health, (2) coordinate the international activities of both the intramural and extramural programs of the categorical Institutes, (3) provide a central point of contact and liaison with other Federal agencies, and (4) promote a community of interest at the NIH in international health.

SUGGESTED SPENDING LEVELS

Question: Last year the Committee asked you, Dr. Fredrickson, to submit for the record what your recommendations would be in terms of what each Institute would receive if we provided various amounts of funding. We hate to put you on the spot again this year but for our information please show us how you would increase the various Institute budgets and program budgets at NIH if you were to receive an additional $50 million, an additional $100 million, or $150 million more.

Answer: If the Committee adds an additional $150 million, NIH would establish the following priorities which divide roughly into three $50 million increments.

First Priority - ($50 million increase)

This increment would be distributed to:

- Increase the stipends paid under the National Research Service Awards (NRSAs) for the number of trainees reflected in the 1980 budget proposal. This has been encouraged by the new NRSA Act and the concept is supported by all the Institutes.

- Allow those Institutes funding less than 21 percent of approved competing research project grant applications to achieve this approximate level.

Second Priority - ($100 million cumulative increase)

This increment would be used to further increase our support of Investigator-initiated research (research project grants). In particular, funds would be used to:

- Permit those Institutes funding less than 25 percent of approved competing research project grant applications to achieve this approximate level.

- Further develop the Chemical Information System required by the National Toxicology Program.

- Provide for renovations necessary for the interface of the Clinical Center with the new Ambulatory Care Research Facility.

Third Priority - ($150 million cumulative increase)

The objective with the third increment would be to continue the development of our capability to fund investigator-initiated research (research project grants) and to expand our efforts in select research areas. Specifically, funds would be programmed to:

- Permit the Institutes to fund approved competing research project grants to an approximate level of 27 percent.

- Increase the National Cancer Institute efforts in the testing of chemicals, the development of testing methodology, the maintenance of National Toxicology Program resources, and to

emphasize a new program on the biologic effects of ionizing radiation.

- Expand the efforts of the National Institute of Allergy and Infectious Diseases in the area of risk assessment related to recombinant DNA research.

- Provide initial support for research support services and the purchase of equipment for the new National Institute of Environmental Health Sciences facility in North Carolina.

- Provide the National Institute of Neurological and Communicative Disorders and Stroke support for the funding of approved research grant proposals for positron emission transverse tomography (PETT).

- Allow the National Institutes of Health to increase support for grants and clinical investigation awards in aging, and to increase the number of women in the Baltimore Longitudinal Study.

- Provide the National Heart, Lung, and Blood Institute additional resources to expand activities in the area of prevention, for example a clinical trial of hypertension in the aging and a study of the role of salt and obesity in hypertension.

- Increase the National Institute of Arthritis, Metabolism, and Digestive Diseases support in areas of skin, kidney and digestive diseases.

- Support a National Eye Institute expanded cooperative clinical study on photocoagulation treatment of diabetic retinopathy.

The following table shows how we would distribute the $150 million by the Bureaus, Institutes, and Divisions.

NATIONAL INSTITUTES OF HEALTH
Allocation of $150,000,000 Over 1980 President's Budget
(dollars in thousands)

	1980 President's Budget	1st $50,000,000	2nd $50,000,000	3rd $50,000,000	Total	1980 Revised Estimate
National Cancer Institute	$936,958	$4,000	$3,200	$19,200	$26,400	$963,358
National Heart, Lung, and Blood Institute	507,344	12,700	11,000	3,500	27,200	534,544
National Institute of Dental Research	66,118	600	--	200	800	66,918
National Institute of Arthritis, Metabolism & Digestive Diseases	305,746	4,700	8,500	3,500	16,700	322,446
National Institute of Neurological & Communicative Disorders & Stroke	212,322	1,500	--	5,700	7,200	219,522
National Institute of Allergy & Infectious Diseases	190,202	8,200	3,100	4,100	15,400	205,602
National Institute of General Medical Sciences	280,378	8,600	11,100	3,000	22,700	303,078
National Institute of Child Health and Human Development	204,381	6,400	5,700	1,400	13,500	217,881
National Eye Institute	104,528	1,300	2,000	2,100	5,400	109,928
National Institute of Environmental Health Sciences	79,012	1,500	1,100	4,300	6,900	85,912
National Institute on Aging	56,510	400	--	3,000	3,400	59,910
Division of Research Resources	154,199	100	--	--	100	154,299
Fogarty International Center	8,989	--	--	--	--	8,989
Subtotal	3,106,687	50,000	45,700	50,000	145,700	3,252,387
National Library of Medicine	41,431	--	1,300	--	1,300	42,731
Office of the Director	21,062	--	--	--	--	21,062
Buildings & Facilities	3,250	--	3,000	--	3,000	6,250
Total	3,172,430	50,000	50,000	50,000	150,000	3,322,430

INNOVATIVE RESEARCH

Question: We are hearing more and more complaints about investigators outside the mainstream of NIH not receiving adequate funding.

What efforts have been made in all of the Institutes to spur innovative research programs?

Answer: All of the Institutes engage in forward planning related to their mission areas. In those instances where it is clear that particular avenues of research required special attention the Request for Application (RFA) is prepared. The RFA describes a specific research area requiring attention and is broadly disseminated throughout the scientific community. It is designed to attract new investigators, or established investigators with new or novel approaches into a designated research area. In FY 1978, 51 RFA's were issued together with 92 program announcements. The program announcement differs from the RFA in that it is an expression of general program interest, as opposed to a specific area, and does not indicate whether or not monies have been set aside to support the resulting proposals.

PEER REVIEW

Question: Last year the Committee asked the Office of the Director to report on ways in which the NIH study group and peer review councils can be stimulated to place greater emphasis on supporting newly-emerging researchers and investigator-initiated, innovative approaches to resolving research questions.

Would you please give the Committee some of your comments and recommendations which came from this study.

Answer: In the current peer review study team report of February 1978, specific recommendations were made to the Director of NIH to encourage the consideration of innovative research efforts. One recommendation was that NIH consider the feasibility of increasing support for unconventional research proposals. The Committee directed the Director of NIH to report to the Committee within 90 days on ways in which the NIH study group and peer review councils could be stimulated to place greater emphasis on supporting newly-emerging researchers and investigator-initiated innovative approaches to resolving fundamental research questions.

The NIH Grants Peer Review Study Team made four recommendations concerning the identification and funding of innovative research proposals. As summarized in the document "Decisions by Director NIH on Recommendations of Grants Peer Review Study Team - February 8, 1978" only one recommendation of four was considered practical: that initial review groups (IRG's) be requested to identify applications they considered to be especially creative or innovative whether or not the applicants so identified them. The remaining three recommendations which would require the applicant to identify innovations, that the reviewers provide a separate statement on the innovation aspects of the work, and that money be set aside for speculative research, were considered either duplicative of current procedure or programmatically unsound.

The Division of Research Grants (DRG) which is the primary unit responsible for conduct of initial review holds orientation meetings for new IRG members. The importance of identifying and encouraging innovative approaches to research is emphasized. A similar orientation is provided for new National Advisory Council members.

DRG through its study sections sponsors at least a half-dozen workshops a year to discuss a particularly promising new area of research, ideas or techniques. Scientists considered to be in the vanguard present the latest developments in the field including not only what is being done but also what must be done. In order to reach more than the attendees the results of the workshops are disseminated through the scientific media.

In the past several years the NIH Institutes have adopted the use of issuing Requests for Applications (RFA) which are broadly distributed throughout the scientific community. The RFA describes a particular area requiring attention and is designed to attract new investigators or established investigators with new or novel approaches into a designated area. Applications received in response to an RFA are so marked by the investigator and considered, if approved, in special competition for the funds set aside for that purpose. 51 RFA's were issued in fiscal 1978 together with 92 program announcements.

PEER REVIEW

Question: On February 8, 1978, you sent to the Committee a booklet entitled "Decisions by Director NIH on Recommendations of the Grants Peer Review Study Teams."

What have you done to implement these recommendations in Fiscal 1979 and what are your plans for Fiscal 1980?

What kind of progress are you making in this area?

Answer: The report of the Grants Peer Review Study Team contained 69 recommendations. To summarize, three recommendations required no action, three recommendations were not concurred in by the Director of NIH, leaving 63 recommendations requiring action. We believe we are making significant progress in implementing these recommendations. To date, 20 recommendations have been implemented, 24 recommendations are in the process of implementation during 1979 and 19 recommendations are in process or will be in process of implementation in 1980.

The following is a summary of the status of the implementation of the principal recommendations:

Appeals Mechanism

The GPRST recommended that a formalized NIH peer review appeals system be established to correct or eliminate real or perceived deficiencies in peer review of grant applications. Pending study of legal, administrative and fiscal issues related to instituting a formal appeals mechanism, a notice describing the Informal Appeals Process has been published in the August 4, 1978 issue of the NIH Guide for Grants and Contracts.

Improved Communication with Applicants--Release of Summary Statements

The GPRST recommended that following completion of peer review of a grant application, the summary statement ("pink sheet") with priority score displayed be released to the principal investigator. A notice has been published in the August 18, 1978 issue of the NIH Guide for Grants and Contracts stating that following the September-October 1978 Council/Board meetings, and routinely thereafter following each round of Council/Board meetings the summary statement with priority score displayed will be sent to the principal investigator. Accompanying each summary statement will be an attachment describing the procedure for arriving at the raw and normalized priority score and a brief comment concerning the factors entering into the funding decision.

Reduction of Workload

The GPRST made a series of recommendations related to the workload of peer review groups, NIH staff and applicants to NIH for grant support. A number of actions affecting workload reduction are being developed for implementation and will be reported on later in FY 1979 and FY 1980. Actions related to simplification of grant applications are reported below:

- A notice was published in the June 9, 1978 issue of the NIH Guide for Grants and Contracts reminding applicants regarding preparation of shorter applications.

- The DRG Application Forms Revision Committee has completed a revision of research grant application form PHS 398. This is awaiting clearance by OMB.

- Revision of the application form 2590--(application for committed support) will be completed on or about May 1, 1979.

- Revision of National Research Service Award Application Forms

  1. Revision of Individual Fellowship Application (PHS 416 series) has been completed and is presently at OMB for clearance.

  2. Institutional Training Grant Application (PHS 6025) has been revised and will be forwarded to OMB for clearance.

  3. Research Career Development Award Application (PHS 2557-1). Review of the revised form has been completed and it will be incorporated into application form PHS 398.

Opening Up the Process for Nomination and Selection of Non-Federal Advisors for Service on Initial Review Groups and Councils

The GPRST recommended that procedures for nomination and selection of peer review members be widely publicized and opened up to invite nominations from the scientific community.

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- An announcement was published in the January 31, 1979 issue of the NIH Guide for Grants and Contracts publicizing the request and procedures for Nominations for Members of NIH Scientific Review Groups. Concurrently an announcement appeared in the February 23, 1979 issue of Science and in the February 1979 issue of Federation Proceedings also publicizing NIH's request and procedures for nominations for members of NIH Scientific Review Groups.

- A similar announcement regarding nominations for Council/Board members will shortly be completed and will be similarly publicized.

Conflicts of Interest

The GPRST made a series of recommendations related to clarifying and strengthening aspects of conflicts of interest for peer review members.

An NIH staff document entitled "Avoiding Conflicts of Interest for Peer Review Advisors -- Invitation Letters to Public Advisory Groups Members and Processing of Conflict of Interest Forms" has been developed and made available as guidance for NIH staff. An announcement will shortly be published in a forthcoming issue of the NIH Guide for Grants and Contracts so that the substance of this guidance may be broadly known and understood throughout the scientific community.

Revision and Updating of Instructions Regarding Peer Review Procedures

The GPRST made several recommendations relevant to updating and modifying specific instructions regarding peer review procedures.

Revision and updating of NIH Peer Review procedures to assure inclusion of approved recommendations of GPRST is proceeding and is anticipated for completion as a series of procedural instruction documents by June, 1979.

"Single Priority Score" Convention

The GPRST recommended that a "single priority score" convention be adopted for use throughout NIH.

A Priority Score Committee to review priority score procedures and recommend a single priority score convention at NIH has completed its study. The report and recommendations are now under review for implementation.

Orientation of Peer Review Members

The GPRST recommended that NIH hold annual orientation sessions for all initial review group and council members particularly new members, so as to place peer review in perspective and to inform reviewers of their functions, duties and responsibilities.

An Orientation Committee has been activated to study procedures and materials to be included in orientation of Peer

Review Groups. A report is anticipated by June 1979.

PEER REVIEW

Special Studies Related to Reviewer Behavior in the Peer Review Process

The GPRST recommended that several special studies be undertaken to evaluate reviewer group and individual behavior as it may affect actions during the peer review process.

Because of the complexity and long range nature of the proposed studies, several staff members have been asked to review the recommendations to determine if experimental procedures can be devised to meet the objectives. A report will be made in FY 1980.

DIVISION OF RESEARCH GRANTS

Question: What has the budget been for DRG, that program at NIH which initially reviews all grant proposals, for the past five years? Because of the tremendous influx of the new grant proposals to NIH in the past few years, while at the same time DRG has been held at a constant level in terms of people and dollars, isn't this having a detrimental effect on peer review?

Answer: The following table displays the DRG funding level from 1976 through 1978.

(in thousands)

1976 Actual	1977 Actual	1978 Actual	1979 Estimate	1980 Estimate
$10,197	$10,900	$11,635	$13,299	$14,523

The budget level for DRG has had no significant increase in the past 3 years. This has resulted in a relatively constant level of personnel which, in light of the increasing work load, has made maintenance of the quality of the peer review system difficult.

The number of grant applications reviewed by DRG increased from approximately 8,200 in 1969 to about 18,000 in 1977. Over the same period, the number of study sections increased only from 48 to 50. Both the mounting number of applications and the need to document scientific and administrative review in increasing detail, have placed a severe work load, not only on the DRG staff, but also on the consultants who constitute the peer review team. Although not easily measured, without relief, the potential for erosion of the system exists because the unprecedented work load shows no sign of diminishing.

Question: Is the reivew process becoming even longer in terms of evaluation and funding of research grants because DRG is so weighted down?

Answer: No. The review process itself has not been extended. As mentioned above, however, it is the continued high quality of the review process that is in jeopardy. For example, a study section

which had 80 applications to review during a single meeting (usually a three-day period) in 1970 would have as many as 160 applications to review within the same period in 1978. We have streamlined every procedure possible to accommodate to this rise in numbers without lengthening the time from application receipt to notice of action.

SIZE AND NUMBER OF PEER REVIEW PANELS

Question: It appears that the Administration is attempting to reduce, or, at best, to maintain at present levels the number and size of peer review panels in the DRG at NIH. We have found that in the last four to five years the number of grant proposals submitted to NIH has nearly doubled to over 18,000. It seems natural that the number and size of peer review panels should be growing because of the tremendous work load of proposals which individual review panel members must contend with.

What are you doing in this area? What increase in size and number of review panels would be required to ensure that members of each panel would have legitimate numbers and manageable numbers of grants to review?

Answer: Several actions have been taken to alleviate the heavy burden of the NIH peer review system. In August 1978, NIH requested approval from the Secretary of HEW to establish additional study sections. Approval has now been received for four of these. The new groups will review grant applications in areas now receiving considerable scientific and public attention and which are expected to generate intense research activity in the foreseeable future. The creation of these study sections will reduce the work load of several of the most heavily taxed panels within the NIH grants peer review system. Clearly, their creation will do much to maintain the quality of the application review process. Also, we are currently reconsidering the need for, and the feasibility of, establishing several additional new study sections.

Other positive steps which have been taken by DRG are:

- Since May 1978, DRG has increased the level of staff in support of the grants peer review process. Seven scientists have been recruited to serve as executive secretaries of study sections. Fifteen clerical positions have also been filled. These actions have contributed substantially toward helping peer reviewers deal effectively and efficiently with their heavy work load.

- NIH staff have discussed the work load situation on many recent occasions with members of numerous professional societies and research institutions in order to encourage briefer applications. For example, discussions have been held with the Association of American Medical Colleges, the Federation of American Societies for Experimental Biology, and the Intersociety Council of Biology and Medicine. Further, an announcement in the June 1978 NIH Guide for Grants and Contracts reminded readers that it is quality, not quantity, that the NIH seeks in applications.

- Beyond these interim measures, the NIH has submitted to the Office of Management and Budget (OMB) a proposed revision of the standard grant application form (PHS-398). All DRG study section members were consulted prior to modifying the application without jeopardizing the presentation. Page limitations have been proposed for several sections; the instructions for other sections have been rewritten to eliminate redundancy. Having concise yet complete information in grant applications will help to lessen the burden on reviewers. The simplified requirements will be published in the NIH Guide for Grants and Contracts and other periodicals as soon as OMB clearance is received. The announcement will also be inserted in the grant application kits. These revised instructions should not only effect an immediate reduction in paperwork for both applicants and reviewers but also should set the stage for introduction of the new standard grant application form later in Fiscal Year 1979.

- A study group within the DRG is now considering ways to expedite the preparation of summary statements prepared after peer review. Assessment of the cost-effectiveness of introducing word processing technology and modifications in paper flow are major objectives of the study.

In summary, NIH has taken several steps to reduce the overload on its peer review system, and will continue to address the situation.

RESEARCH PROJECT GRANTS

Question: As funding becomes tighter and tighter, what has and will NIH be doing to see to it that a higher percentage of the budget actually goes into research projects?

Answer: NIH has made a conscious effort supported by the Congress to increase that portion of the budget which goes into research project grants. The research project grants portion of the budget has increased from 39 percent in Fiscal Year 1977 to 43 percent in 1979 and 1980.

LONGER GRANTS

Question: There have been reports, Dr. Fredrickson, that you and Dr. Upton and other NIH directors favor grant awards for longer periods than has been the practice in recent years. Would you comment on this and give us your rationale please?

Answer: During the past year, the senior staff of the NIH has been studying the desirability and feasibility of longer award periods. At present, the average award period for individual research project grants is 3.1 years. For program project grants and center grants, the average award period is 3.8 years. We believe longer award periods could be of substantial benefit to both our programs and the awardee institutions if this could be brought about in a way that did not compromise the quality of scientific review or create unrealistically large obligations against future years' appropriations. We must be sure to effect a reasonable balance between short-term and long-term considerations.

NIH peer review groups for grant applications often recommend an award period shorter than that requested. These reductions generally occur when (a) the applicant investigator has not provided a convincing plan for more than two or three years of research activity or (b) the objective of the proposed project is considered important but there is sufficient uncertainty about the efficacy of the approach to warrant an early review of progress. In addition, NIH staff, when making awards, must be continually sensitive to the fact that future funding levels may not be adequate to support a reasonable number of meritorious new and competing renewal applications while simultaneously honoring the commitments established by present awarding actions.

When viewed individually, short-term awards seem prudent, but when viewed in the aggregate, they are seen to produce at least three undesirable effects. First, by shortening the reapplication cycle, short-term awards increase the time and effort that investigators must devote to seeking research funds; in many cases, the result is a decreased level of research activity and lower scientific productivity. Second, short-term awards frequently introduce serious uncertainty about the prospects for continuity of support and thus interfere significantly with career plans; new investigators are especially vulnerable to this effect. Third, short-term awards lead to higher numbers of competing renewal applications; this adds to the already severe workload of the NIH grants peer review system, thereby threatening its quality and increasing its costs.

We are now conducting an extensive series of data analyses and forecasts to understand the positive and negative consequences of potential policy changes with respect to the length of award. We will be pleased to share the results of our efforts with the Committee.

TERMINATION FUNDS

Question: In Fiscal 1980, how much money will be available from grants and contracts which expired in Fiscal 1979? (Break out by Institute.)

Answer: We estimate that approximately $341 million will be available in 1980 from research project grants and contracts which are terminating or converting to competing status. However, at the same time, the competing research project grant and contract awards made in 1979 will convert to non-competing status in 1980. Consequently our total non-competing requirements for 1980 are $1,489 million, an increase of $232 million over 1979. The data by Institute will be supplied for the record.

NATIONAL INSTITUTES OF HEALTH

Research Projects
(in thousands)

	1979	Noncompeting Terminating	Competing Converting to Noncompeting	1980 Total
NCI				
Noncompeting...	$177,468	-$58,155	+$104,271	$223,584
Competing.....	99,306			59,190
Total.....	276,774			282,774
NHLBI				
Noncompeting...	169,000	-61,389	+80,118	187,729
Competing.....	76,303			48,129
Total.....	245,303			235,858
NIDR				
Noncompeting...	19,164	-6,387	+8,069	20,846
Competing.....	7,080			4,985
Total.....	26,244			25,831
NIAMDD				
Noncompeting...	130,800	-47,416	+52,800	136,184
Competing.....	54,401			44,537
Total.....	185,201			180,721
NINCDS				
Noncompeting...	59,082	-24,550	+44,258	78,790
Competing.....	43,007			23,299
Total.....	102,089			102,089
NIAID				
Noncompeting...	67,472	-19,278	+46,198	94,392
Competing.....	42,349			16,085
Total.....	109,821			110,477
NIGMS				
Noncompeting...	112,150	-29,565	+81,628	164,213
Competing.....	81,414			35,860
Total.....	193,564			200,073
NICHD				
Noncompeting...	67,344	-22,897	+39,058	83,505
Competing.....	39,058			23,794
Total.....	106,402			107,299

Research Projects (cont.)
(in thousands)

	1979	Noncompeting Terminating	Competing Converting to Noncompeting	1980 Total
NEI				
Noncompeting..	$42,388	-$8,939	+$27,619	$61,068
Competing.....	29,880			9,566
Total.....	72,268			70,634
NIEHS				
Noncompeting..	19,715	-9,110	+8,769	19,374
Competing.....	8,656			5,448
Total.....	28,371			24,822
NIA				
Noncompeting..	19,342	-11,071	+14,899	23,170
Competing.....	12,922			8,627
Total.....	32,264			31,797
Total, NIH				
Noncompeting..	883,925	-298,757	+507,687	1,092,855
Competing.....	494,376			279,520
Total.....	1,378,301			1,372,375

NOTE - Noncompeting includes administrative supplementals

Contracts
(in thousands)

	1979	Renewal Terminating	New Converting to Renewal	1980 Total
NCI				
Renewals.....	$202,603	-$23,478	+$31,456	$210,581
New.....	33,287			15,212
Total.....	235,890			225,793
NHLBI				
Renewals.....	91,979	-2,433	+3,250	92,796
New.....	3,000			--
Total.....	94,979			92,796
NIDR				
Renewals.....	2,848	-3,219	+2,200	1,829
New.....	2,200			3,219
Total.....	5,048			5,048
NIAMDD				
Renewals.....	13,592	--	+2,867	16,459
New.....	1,935			--
Total.....	15,527			16,459
NINCDS				
Renewals.....	16,809	-2,080	+2,830	17,559
New.....	2,510			1,760
Total.....	19,319			19,319

Contracts (cont.)
(in thousands)

	1979	Renewal Terminating	New Converting to Renewal	1980 Total
NIAID				
Renewals	$14,610	-$2,625	+$3,915	$15,900
New	3,685			1,435
Total	18,295			17,335
NIGMS				
Renewals	68	-48	+577	597
New	732			203
Total	800			800
NICHD				
Renewals	14,889	-7,125	+11,501	19,265
New	11,501			8,519
Total	26,390			27,784
NEI				
Renewals	5,220	--	+280	5,500
New	610			500
Total	5,830			6,000
NIEHS				
Renewals	4,125	-1,036	+4,203	7,292
New	4,167			1,000
Total	8,292			8,292
NIA				
Renewals	2,504	-392	+2,132	4,244
New	2,099			256
Total	4,603			4,500
DRR				
Renewals	4,152	--	+93	4,245
New	98			--
Total	4,250			4,245
Total, NIH				
Renewals	373,399	-42,436	+65,304	396,267
New	65,824			32,104
Total	439,223			428,371

INDIRECT COSTS IN RESEARCH GRANTS

Question: When NIH awards a research grant there is a provisional indirect cost rate applicable to it. When the grant is partially or wholly completed, that indirect cost rate is often adjusted upwards. Where does an NIH Institute get the money to add on to the agreed-upon grant amount after the original cost has been included in its budget allocation?

Answer: When indirect cost rates are adjusted upward, the funds come from within the total available to the Institute.

INDIRECT COSTS

Question: Dr. Fredrickson, how much is spent each year out of the total amount awarded these grants at NIH for indirect costs?

Answer: During Fiscal Year 1978, $1,529,213,025 was obligated for research grants and $416,402,221 or 27.2 percent of that was awarded for indirect costs.

Question: In your opinion, what could or should be done to hold this cost down?

Answer: During the period from 1968 to 1976 indirect costs rose from 19.1 percent to 27.0 percent of total dollars awarded for research grants. However, the rate has since leveled off and represented 27.2 percent in Fiscal Year 1978. Given rising costs, in particular for energy, as well as the increasing socioeconomic concerns of the public and Congress in such areas as civil rights, protection of human subjects, animal welfare, handicapped individuals, etc., grantee institutions have had to incur correspondingly higher administrative costs. These costs are an indispensible part of the total cost of conducting research. With few exceptions (for example, foreign grants, grants to individuals and training grants) NIH supports paying the full costs of conducting research less the required level of cost sharing. Under the circumstances, it is difficult to conceive how indirect costs might be held down.

Question: What impact will the proposed OMB indirect cost regulations (the so-called A-21 regulations) have on institutions receiving NIH grants?

Answer: In general, the new cost principles will provide for more consistency in the way individual elements of indirect costs are allocated. Since educational institutions will in most cases now have to distribute indirect costs to sponsored agreements on the basis of modified total direct costs, comparisons of individual indirect cost rates will be facilitated.

The new principles require that the total cost of operating specialized service facilities, e.g., a computer center or vivarium include both direct costs and the facilities' allocable share of indirect costs. In the past, operation and maintenance (O&M) costs, depreciation, etc., related to the operation of such specialized facilities were not considered in establishing a charge rate for their use; instead, they were included with other O&M-type expenses and charged to projects proportionate to their contribution to the institution's indirect cost base. This change will result in an overall reduction in indirect cost rates, but will not effect the total amount charged to Federally-sponsored projects because this decrease in indirect costs will be offset by a corresponding increase in direct costs for use of the specialized service facilities.

The new principles may result in a reduction of the costs of student administration and services, e.g., dean of students, registrar, student infirmary that were formerly allocated to research projects. The new principles now require that student administration and services costs should be allocated to instruction unless well-documented cost studies demonstrate that some of these expenses support students in their capacity as employees on research grants.

DUPLICATION AND OVERLAP

Question: With a great deal of inner Institute programs and crosscutting research, what are you doing to make sure that there is no duplication of programs or overlapping efforts at NIH?

Answer: The concern of overlap and duplication is one that is always with us. Much is done at NIH both informally and formally to prevent unnecessary duplication. Examples of informal mechanisms include the day-to-day collaboration of individual bench-scientists of the different Institutes; discussions and presentations of the Institutes' programs at various meetings, such as the NIH Scientific Directors meetings; and one Institute program staff discussing with another Institute areas of mutual interest.

Examples of more formal arrangements we are using include the annual forward plan reviews held by the Director, NIH, and the establishment of coordinating committees for such cross-cutting areas as diabetes, arthritis and nutrition. These coordinating committees are responsible for reviewing the state-of-the-art, opportunities, and Institute plans to carry these out and to make recommendations to the Director on future program directors. To improve the management of these broad research programs even more, I have recently instituted a new approach for the diabetes program. I have strengthened and expanded the role of the Associate Director for Diabetes of the National Institute of Arthritis, Metabolism, and Digestive Diseases in the overall coordination effort for diabetes for NIH.

To strengthen and more effectively carry out our efforts in the "transfer" of knowledge to the health care system, we have established an Office of Medical Applications of Research to coordinate these activities throughout NIH.

CENTERS

Question: In your opinion, is it harder for widely-distributed centers across the nation to communicate back and forth and to ensure there is no duplication being conducted?

Answer: Distance is not a problem. Proximity doesn't necessarily enhance communication; the basic issue is whether the people who need to communicate with each other make the effort to do so. In establishing centers we have to go where the competent investigators are. Also, there is value in having diverse settings for centers; diversity supports a desirable independence of thought. Fundamentally, the problem of communication in centers is no different from the general problem of communication in science. If anything, communication among members of centers is better than it is among scientists at large, because the network of centers funded by any particular institute of the NIH is better organized and the individual bureaus, institutes and research divisions make specific efforts to promote communication among center grantees. Furthermore, centers tend to be oriented around central themes, and the people who work in these specified areas know each other. Some duplication is necessary in the sense of having the same work done in different places in oder to make sure that the findings are repeatable. Also, we often want a certain amount of controlled duplication, because a

problem is more likely to be solved if a number of investigators are simultaneously attacking it from different points of view. This kind of duplication might better be described as intellectual competition, and it is as valuable a spur in science as it is in other aspects of American life. To eliminate it in the name of eliminating duplication would be a tragic error.

Within centers, unnecesary duplication is even less likely than it is in the scientific world at large because most of our programs provide a structure which is specifically designed to increase communication. From the beginning, the application which a center submits outlines the research which will be carried out in it, and consideration of possible duplication is part of the peer review process. Program officers within the institutes of the NIH are very familiar with the scientific activity in the centers which are funded in each of their programs, and they work to avoid unnecessary duplication.

CENTERS

Question: I would like some of you Directors to give us specific examples of what you do to ensure that there is no duplication of research at your centers programs and, in terms of what is going on at the NIH campus. And how the information found is relayed from the centers to other people across the Nation:

Answer: Answers are provided for National Cancer Institute (NCI), National Heart, Lung, and Blood Institute (NHLBI), National Institute of Neurological and Communicative Disorders and Stroke (NINCDS), National Institute of General Medical Sciences (NIGMS), and National Institute of Child Health and Human Development (NICHD).

NCI

Almost all of the research performed at cancer centers is supported by grants and contracts from NIH, other governmental agencies, the American Cancer Society, and other private agencies. The mechanisms for minimizing undesirable duplication of research between various centers and between any of the centers and NIH are, therefore, the same as those mechanisms that are used at institutions that are not cancer centers. These mechanisms include:

- The knowledge of the investigator that his/her grant proposal undergoes peer review and that if the grant is duplicative of work already performed, the peer review group (study section) will not award the proposal a priority high enough to assure funding.

- Investigators at the National Cancer Institute will not initiate research duplicative of work already performed because it is not in their professional best interest to do so. These investigators depend upon continued performance of innovative research in order to assure sustained support at the National Cancer Institute.

- The National Cancer Institute's grant and contract program directors are aware of on-going or recently completed research and take this information into account in making

funding decisions for specific grants.

- These same program directors are involved in the generation of Requests for Proposals (RFP) for contracts and, based on their knowledge of the on-going research in the field, forestall the issuance of RFP's that would lead to unnecessary duplication.

It should be emphasized that the concern is unnecessary duplition. Duplication is an important and desirable part of the scientific process. Conclusions drawn from the research of one investigator cannot be considered "fact" until the research results have been independently duplicated by two or three other scientists. This type of duplication is crucial to scientific progress; duplication becomes excessive only when a large number of investigators are all doing the same research and obtaining the same answers. This is what the present NIH system rather successfully avoids. Research findings from centers are transmitted to other investigators by the usual means of scientific communication; namely, presentation and discussion of results at scientific meetings, followed by publication in journals. Research meetings are exceedingly important in the process of avoiding unnecessary duplication as they provide the forum at which recent experiments are presented, thus alerting colleagues to work already performed but not yet published in the literature. Investigators at the NCI and other NIH institutes must participate fully in these meetings in order to stay current and to insure that the results of their experiments are made available to other investigators in a timely fashion, as well as to assure that NIH scientists hear early reports of research results from other investigators and do not initiate unnecessarily duplicative studies.

NHLBI

The NHLBI centers programs (Specialized Centers of Research, Comprehensive Sickle Cell Centers, and National Research and Development Centers) are designed specifically to complement and not duplicate other programs supported by the Institute.

Many of the disease problems which comprise the Institute's mandates are of such magnitude and complexity that their solution requires a coordinated effort which encourages multiple research institutions and diverse scientific and technical disciplines to work together.

Designed as coordinated activities, the centers programs facilitate exchange of ideas and information among participating centers with mutual interests. In fact, these programs constitute a national network.

In order to ensure that there is no duplication in the center programs the Institute uses the following mechanisms.

Institute guidelines: Guidelines for Centers support emphasize communication. For example, the Division of Lung Diseases includes in its Announcement for Specialized Centers of Research the statement that -

"The sponsoring institution, SCOR director and responsible

investigators must be committed . . . to maintaining close liaison with the Division of Lung Diseases . . . the Division will provide, as part of the SCOR grant, funds for SCOR coordination, which will make it possible through visits or workshops for investigators in different SCOR groups to meet and discuss problems of mutual interest.

This relationship with the Division is intended to be supportive not restrictive, but the special features of the SCOR grant require close interaction between the Division and SCOR group. . ."

Coordination Funds: Funds are provided explicitly to foster coordination among centers. They are reserved for such activities as meetings of center directors; center-sponsored workshops; visits to centers by consultant scientists; travel for center participants to other centers working on problems of mutual interest; and travel to non-center laboratories for purposes that will benefit the center (e.g., to learn a new technique).

Reports: The Institute has developed a format for the annual progress report that lends itself to general community dissemination of appropriate findings. The report provides (a) a summary of accomplishments for the year, (b) highlights of three or four of the most significant achievements, and (c) a description of coordination activities.

Workshops and Task Forces: The centers program workshops are justified in terms of the national research scene - they must include not only center participants, but invited participants from the scientific community. The reports from the workshops are disseminated to the scientific community.

The purpose of center coordination is not only to avoid duplication but to facilitate problem solving. For example, certain patients with uncomplicated acute myocardial infarction are being discharged as early as seven days after admission. A program testing the feasibility of early discharge has originated in one of our centers programs. The definition and development of criteria for this reduction of hospital stay was formulated by coordination among centers and now a coordinated effort is evaluating and analyzing groups of patients. The early results suggest that early ambulation and discharge of patients with uncomplicated myocardial infarction speeds up and enhances total rehabilitation and leads to enormous economic savings.

NINCDS

Like individual grantees, scientists in NINCDS-supported clinical research centers engage in the usual interchange of ideas and research progress at the various annual scientific meetings across the country. But beyond this, the NINCDS sponsors and requires annual or biennial meetings of the center directors and selected staff in each clinical research field, precisely to share problems and progress and to avoid duplication. By these two mechanisms findings are promptly relayed to other investigators across the country, and any major advances are shared publicly. Since each

center grant is awarded for not more than 3 or 4 years, each center is subject to periodic scientific peer review by study section and program relevance review by the NINCDS Advisory Council. At each such review the question of duplication of effort is carefully considered.

NIGMS

NIGMS relies primarily on two procedures to ensure that duplication of research does not occur in its center grants program. First, scientific peer review of center grant proposals includes an evaluation of the originality of the proposals. Second, annual progress reports are used by Institute staff to assess whether the center grant research proceeds according to the proposed plan for original work. Information about the activities supported by NIGMS research center grants is shared in three ways: (1) research findings are published in appropriate scientific journals, (2) annual progress reports are submitted to the sponsoring program, and (3) periodic meetings are held at which all the principal investigators in a particular field exchange ideas and research findings and discuss directions for future research. Published articles are read by all respected physicians and scientists in the discipline and research findings are integrated into medical practice as warranted.

NICHD

Duplication is avoided by careful program administration and by ensuring effective communication. Administratively, the scientific review committees which evaluate proposals for center grants make special efforts to avoid duplication of research effort. This is followed up by staff monitoring to ensure that no significant redundancy exists among programs.

Communication between and among Centers in our various programs is well established and effective. Center Directors meet regularly to discuss issues of common concern and to plan future directions for research. At the meetings of Center Directors, scientific presentations are made covering overall aims and salient features and developments of ongoing studies. In addition, the Mental Retardation Research Centers (MRRCs) also report on current research activities and products in newsletters or in annual reports prepared by the respective Centers. These are distributed to the other Centers, government agencies, institutions of higher learning, and concerned public agencies. Scientific conferences involving MRRC research personnel together with non-Center scientists are convened annually by the NICHD to consolidate and develop research thinking and strategies in specific and critical areas of research activity concerned with mental retardation. The proceedings of each conference are published in book form and appear in the NICHD-Mental Retardation Research Centers Series. Eight publications have been produced and disseminated as part of the Series.

There is no overlap between the Centers and the Intramural Research Program. In the design of center programs and intramural research programs, care is taken through use of special study sections in the case of centers, and the Board of Scientific Counselors for the intramural program, to eliminate duplication of research efforts. This was put into practice most recently with the

establishment of the Major Research Programs (MRP) grants, when special attention was given to the avoidance of overlap with the NICHD Intramural Research Program. In the population sciences, joint conferences are held annually between NICHD Intramural and extramural scientists and scientists from other parts of NIH as well as from the Centers and other organizations and institutions.

All research whether supported in centers or in individual grants is communicated to the scientific community primarily through publication in appropriate scientific journals and by presentation at scientific/professional association meetings and at other specialized workshops, conferences, etc. Through the NICHD Office of Research Reporting, scientific findings are communicated to a wider audience, including the public at large. Specific examples of what is done to facilitate the rapid dissemination of new and significant information is the sponsoring of conferences or workshops by the Institute either in connection with an annual Center Director's Meeting or in association with a scientific society's meeting. These special meetings are prepared, presented and published through the collaboration of scientists from NIH and scientists from the Centers and other organizations and institutions. In the population sciences, an Inventory and Analysis of Federal Population Research is prepared for both intra and extramural research. This report as well as various annual reports of research findings are widely disseminated to the scientific community, including center directors and individual researchers.

CONSULTANTS

Question: As you may know last year, the Committee began to place tough restrictions on the use of consultants within HEW. In essence, we had found that their funding being spent on consultants has increased from less than $100 million to well over $200 million in fiscal year 1979--we restricted this to $190 million.

We have now found that the Cancer Institute has not been reporting their use of expert consultants as required by the Committee and the Department.

Could you please explain to us why this has not been done?

Answer: Prior to the imposition of the $194,000,000 ceiling on consultant services included in the Senate report on the 1979 Appropriations bill, the Cancer and Heart Institutes were not required to report their use of the expert positions authorized under Sections 409(b) (1) and 413(c)(1), respectively, of the Public Health Service Act. Indeed, these experts were considered to be exempt from policies governing consultants, since they did not conform to the Department's definition of consultant (i.e., experts may work more than 130 days per year and carry out hands-on work, rather than simply providing advice). After the ceiling on consultant services was imposed, it was decided that these experts should be considered as consultants, and thus counted against the ceiling. Since then, the Cancer and Heart Institutes have been reporting their experts.

Question: How do you use these "expert" consultants?

Answer: Our experts are used to perform work of a specific, time-limited duration, which requires the special qualifications of the expert involved. As indicated previously, this is actually "hands-on" work, rather than the provision of advice. The period of appointment is usually one or two years, with the option of renewing the appointment in one-year increments if the need for their expertise continues. Their duties cover a wide range of administrative and scientific areas of expertise, and we have found them to be an invaluable aid in the accomplishment of our mission.

Question: We understand that NIH as a total also has expert consultants they can now hire as does the Heart, Lung, and Blood Institute.

Have any of these positions been filled as of this date?

Answer: The National Heart, Lung, and Blood Institute has about 47 experts on duty as of March 1. The NIH has not yet hired any experts of the 200 we have been authorized, although we expect to begin hiring very shortly. The NIH expert positons will be used by all of the Institutes and Divisions other then NCI and NHLBI.

Question: Isn't this simply another way to get around the personnel ceiling?

Answer: The authority to hire experts, initially in the NCI, then in the NHLBI, and now in the NIH as a whole, was intended by the Congress to complement and augment the scientific capability of our regular, permanent staff. The availability of this authority makes it possible to hire highly and uniquely qualified people quickly, to take advantage of rapidly expanding responsibilities, program growth, or unique opportunities. The use of the expert authority has been a definite asset to both the Cancer and Heart Institutes, and we expect this to be true for NIH as a whole. I feel that our use of the expert authority has been fully consistent with the intent of Congress.

CLINICAL TRIALS

Question: Dr. Fredrickson, how much do you think all of NIH is spending on clinical trials in fiscal year 1979 and what are your plans in 1980?

Answer: The estimated funding level for clinical trials for NIH is $173 million for 1979 and about the same for 1980.

Question: This is getting to be a very expensive portion of the total NIH Budget.

Answer: The portion of the total NIH Budget devoted to clinical trials has stabilized over the past two years. The modest increase from 1978 to 1979 provided for inflationary-costs.

Question: Do you expect that clinical trials funding will continue to grow as rapidly in the future as it has in the past?

Answer: Within the budgetary constraints of a level budget, funding emphasis will be placed on the development of the science base. As basic science progresses, however, opportunities arise for applying the knowledge gained. Clinical trials, are an integral part of biomedical research, and is an important aspect in moving knowledge into health care practice. Such trials enable NIH to carry out its role in improving prevention and treatment of diseases and disabilities. Tighter budgets in the future may make it necessary to make choices more often in this area.

TRAINING

Question: For the record, I would like a table broken down by Institute and program as to how much was being spent in fiscal '78 for training programs, both pre-and post-doctoral and what was spent in '79, and what you are planning in fiscal year 1980.

Answer: The training programs, both pre-and post-doctoral, by Institute for 1978, 1979 and 1980 are shown on the following tables.

NATIONAL INSTITUTES OF HEALTH

Research Training - 1978 Actual Obligations

(dollars in thousands)

	Predoctoral		Postdoctoral		TOTAL	
	FTE*	Amount	FTE*	Amount	FTE*	Amount
NCI.....	525	$5,077	1,011	$15,052	1,536	$20,129
NHLBI.....	258	2,202	1,144	18,990	1,402	21,192
NIDR.....	24	240	143	3,053	167	3,293
NIAMDD....	--	--	863	14,898	863	14,898
NINCDS....	55	605	421	6,760	476	7,365
NIAID.....	134	1,376	434	6,754	568	8,130
NIGMS.....	3,800	35,718	696	10,852	4,496	46,570
NICHD.....	452	3,465	377	6,773	829	10,238
NEI.....	35	285	187	4,358	222	4,643
NIEHS.....	176	1,618	174	2,950	350	4,568
NIA.....	81	802	102	1,583	183	2,385
DRR.....	--	--	31	515	31	515
TOTAL...	5,540	51,388	5,583	92,538	11,123	143,926

* Full-Time Equivalent.

NATIONAL INSTITUTES OF HEALTH

Research Training - 1979 Appropriation

(dollars in thousands)

	Predoctoral		Postdoctoral		TOTAL	
	FTE*	Amount	FTE*	Amount	FTE*	Amount
NCI.....	560	$5,665	980	$14,464	1,540	$20,129
NHLBI.....	280	2,424	1,114	18,768	1,394	21,192
NIDR.....	24	240	133	3,053	157	3,293
NIAMDD....	--	--	795	14,898	795	14,898
NINCDS....	55	605	424	6,760	479	7,365
NIAID.....	108	1,012	396	7,118	504	8,130
NIGMS.....	3,543	36,134	599	10,436	4,142	46,570
NICHD.....	359	3,318	348	6,920	707	10,238
NEI.....	35	280	188	4,363	223	4,643
NIEHS.....	189	1,502	195	3,066	384	4,568
NIA.....	71	781	98	1,064	169	2,385
DRR.....	--	--	33	515	33	515
TOTAL...	5,224	51,961	5,303	91,425	10,527	143,926

Research Training - 1980 President's Budget

(dollars in thousands)

	Predoctoral		Postdoctoral		TOTAL	
	FTE*	Amount	FTE*	Amount	FTE*	Amount
NCI.....	579	$5,829	976	$14,581	1,555	$20,410
NHLBI.....	308	2,687	1,324	22,313	1,632	25,000
NIDR.....	26	286	179	3,912	205	4,198
NIAMDD....	--	--	954	17,877	954	17,877
NINCDS....	55	605	421	6,717	476	7,322
NIAID.....	100	929	383	6,918	483	7,847
NIGMS.....	3,267	33,826	676	11,596	3,943	45,422
NICHD.....	364	2,846	344	6,974	708	9,820
NEI.....	35	280	184	4,363	219	4,643
NIEHS.....	270	2,135	284	4,433	554	6,568
NIA.....	60	630	83	1,354	143	1,984
DRR.....	--	--	33	550	33	550
TOTAL...	5,064	50,053	5,841	101,588	10,905	151,641

* Full-Time Equivalent.

PREDOCTORAL SUPPORT

Question: More and more emphasis is being placed on post-doctoral support research training programs. Shouldn't there be an even mix of pre- as well as postdoctoral support?

Answer: Postdoctoral research traing support at the NIH has been increased primarily to provide a more appropriate balance of pre- and postdoctoral trainees as is suggested by your question. In 1969, NIH supported 8,621 predoctoral and 7,517 postdoctoral trainees. In FY 1977, NIH supported 5,130 predoctoral and 5,068 postdoctoral students. This is felt to be a more appropriate balance of pre- to postdoctoral students and, indeed, is one endorsed by the NAS/NRC report "Personnel Needs and Training for Biomedical and Behavioral Research". It is felt that continued support for postdoctoral students will encourage emerging investigators to attain the needed expertise that will encourage their remaining in academic research.

PAY RATES FOR PRINCIPAL INVESTIGATORS

Question: I note that the National Science Foundation Appropriation Act for last year required that the rate of pay for principal investigators under NSF grants not exceed the pay ceiling for Federal civil servants.

What is NIH's rate of pay for its investigators, both M.D.'s and Ph.D.'s? If the pay rates differ in those two areas, why?

Answer: NIH does not have a rate of pay for investigators. Establishing salary levels is the obligation of the institution to which awards are made and with which the principal investigator has an employer-employee relationship. Institutions may be reimbursed for that portion of an investigator's time which is spent on the funded project.

The average clinical (M.D.) professor at American medical schools has an annual salary of $45,900. The average non-clinical (Ph.D.) professor has a salary of $38,400.

SUPPLEMENTAL REQUEST FOR PAY COSTS

Question: There is no budget request pending for your Pay Costs increases which were mandated by Congress last fall.

How do you expect to absorb these costs and what programs will you have to take the funding from?

How much money will you have to absorb?

Answer: With the exception of the Office of the Director, the Bureaus, Institutes, and Divisions will be absorbing the entire cost of the October 1978 pay raise. This will be accomplished from the savings accruing from the limitations on hiring, consultant services and administrative travel. The balance will be either absorbed within the activity where the cost occurs or by reprogramming from extramural program activities. The Office of the Director will be absorbing approximately $250 thousand of the $1 million required for the pay raise. It is difficult to appreciably absorb more because this appropriation is primarily personnel cost. The balance needed is being achieved by a request for transfer of funds from the National Cancer Institute and the National Heart, Lung, and Blood Institute. The following table displays the absorption and reprogrammings by Institute and program:

FY 1979 Pay Increase Cost
(in thousands)

	Cost of Oct. 1978 Pay Raise	Net Absorption: Amt. Absorbed by Adminis. Act[1/]	Net Absorption: Within Program Where Cost Occurs	Total Amount Absorbed	Reprogramming: From	Reprogramming: To	Reprogramming: Total
NCI	$5,244	$1,780	$3,464	$5,244			-0-
NHLBI	2,078	407	1,541	1,948			
Heart & Vascular Diseases					-130		130
Program Management						+130	
NIDR	658	19	74	93			565
Caries					-91		
Periodontal Diseases					-50		
Restorative Materials					-59		
Craniofacial Anomalies					-187		
Pain and Behavioral Studies					-59		
Soft Tissue, Stomatology and Nutrition					-119		
Intramural Research						+439	
Direct Operations						+93	
Program Management						+33	
NIAMDD	1,739	191	60	251			1,488
Arthritis, Bone, and Skin					-300		
Diabetes, Endocrinology, & Metabolism					-588		
Digestive Diseases and Nutrition					-300		
Kidney Disease, Urology, & Hematology					-300		
Intramural Research						+1,252	
Direct Operations						+180	
Program Management						+56	

FY 1979 Pay Increase Cost - cont.
(in thousands)

	Cost of Oct. 1978 Pay Raise	Net Absorption: Amt. Absorbed By Adminis. Act[1/]	Net Absorption: Within Program Where Cost Occurs	Total Amount Absorbed	Reprogramming: From	Reprogramming: To	Reprogramming: Total
NINCDS	$1,416	$692	$137	$829			$587
Communicative Disorders					-$108		
Neurological Disorders					-254		
Stroke and Nervous System Trauma					-117		
Fundamental Neurosciences					-108		
Intramural Research						+$363	
Direct Operations						+197	
Program Management						+27	
NIAID	1,352	230	95	325			1,027
Immunology, Allergic & Immunologic Diseases					-387		
Microbiology and Infectious Diseases					-640		
Intramural Research						+858	
Direct Operations						+169	
NIGMS	349	99	250	349			-0-
NICHD	1,086	178	--	178			908
Research for Mothers & Children					-908		
Intramural Research						+629	
Direct Operations						+224	
Program Management						+55	

1/ Reflects savings from limitations on hiring, consultant services and administrative travel.

FY 1979 Pay Increase Cost - cont.
(in thousands)

	Cost of Oct. 1978 Pay Raise	Net Absorption: Amt. Absorbed By Adminis. Act 1/	Net Absorption: Within Program Where Cost Occurs	Total Amount Absorbed	Reprogramming: From	Reprogramming: To	Reprogramming: Total
NEI	$476	$250	--	$250			$226
Retinal and Choroidal Diseases					-$57		
Corneal Diseases					-55		
Cataract					-57		
Sensory-Motor Disorders					-57		
Intramural Research						+$179	
Direct Operations						+24	
Program Management						+23	
NIEHS	579	270	$36	306			273
Prediction of Environmental Diseases					-161		
Mechanisms of Environmental Diseases					-112		
Intramural Research						+159	
Direct Operations						+41	
Program Management						+73	
NIA	331	63	34	97			234
Aging					-234		
Intramural						+179	
Direct Operations						+15	
Program Management						+40	

1/ Reflects savings from limitations on hiring, consultant services and administrative travel.

FY 1979 Pay Increase Cost - cont.
(in thousands)

	Cost of Oct. 1978 Pay Raise	Net Absorption: Amt. Absorbed By Adminis. Act 1/	Net Absorption: Within Program Where Cost Occurs	Total Amount Absorbed	Reprogramming: From	Reprogramming: To	Reprogramming: Total
DRR	$141	$34	--	$34			$107
Clinical Research					-$39		
Lab Animal Sciences					-18		
Biomedical Research Support					-38		
Minority Biomedical Support					-12		
Direct Operations						+$63	
Program Management						+44	
FIC	125	30	$95	125			-0-
NLM	809	45	764	809			-0-
					Transfer: From	Transfer: To	Transfer: Total
OD	1,026	114	128	242			784
Proposed Transfer							
NCI							
Treatment Research					-392		
NHLBI							
Heart & Vascular Diseases					-259		
Lung Diseases					-60		
Blood Diseases & Resources					-73		
OD						+784	
TOTAL	17,409	4,402	6,678	11,080	-6,329	+6,329	6,329

1/ Reflects savings from limitations on hiring, consultant services and administrative travel.

NUTRITION

Question: Dr. Fredrickson, there has been an NIH Conference on Nutrition and you have submitted a report to the Committee on what you are doing in the area of Nutrition at NIH.

In your opinion, what programs should we be doing and what efforts or emphasis should we be placing in the area of nutritional programs at NIH?

Answer: The NIH will expand its support in biomedical and behavioral nutrition research and training in the maintenance of health and in the prevention and treatment of disease. Emphasis will be placed on clinical studies in the above areas by many of the Institutes, particularly by the NCI, NHLBI, NIAMDD, NICHD, and NIA. These Institutes have increased their budgets considerably since Fiscal Year 1978.

Question: Please give us some specific examples and funding levels for each of the Institutes for past nutrition efforts and what is expected in Fiscal Year 1980?

Answer: Following are examples of nutrition activities supported in recent years:

- Prevention strategies based on nutrition; nutrition support of the cancer patient; nutrition in cancer etiology; host-tumor interactions and competition for nutrients; and diet and nutrition in the rehabilitation of the cancer patient.

- Nutrition in etiology of arteriosclerosis and of hypertension; achieving and maintaining dietary change; development of food composition tables; and methodology (i.e., collecting, recording, and evaluating dietary data).

- Relationship of sucrose to caries; poor nutrition and periodontal disease; poor nutrition and oral mucous membranes; nutrition in craniofacial malformations and oral-facial structures; and nutrition and salivary gland development.

- Basic physiological studies in nutrients; basic studies on metabolism; studies on obesity, trace elements, and dietary fiber; nutritional support of patients; and nutritional anemias.

- Studies on protein-calorie malnutrition and the nervous system; vitamin B deficiencies and the nervous system; genetic disorders (e.g. phenylketonuria and galactosemia) and the nervous system; specific nutritional problems in the central nervous system; and the nutritional support of patients with stroke.

- Studies on the relationship of malnutrition to infection and the immune system.

- Studies on the nutritional support of patients with trauma and burns.

- Nutrition and fetal development; metabolic capacities of normal infants, low-birth-weight infants, and premature infants; diet modification for low-birth-weight and premature infants; optimum nutrition in developmental years -- infancy through adolescence; nutrition and reproductive potential; nutritional interactions and genetic variability; and the role of nutrients as antecedents of adult disease.

- Vitamin A, B_{12}, and other nutrients in visual processes; diseases of the visual system (e.g., keratomalacia); metabolism of visual cells; and protein changes in the lens.

- The role of nutrients in neurotoxicity, mutagenesis, and teratology; and environmental contaminants in food.

- Nutritional status of the elderly; aspects of increase in life span including dietary manipulations; vitamin supplementation in the elderly; nutrient intake as a consequence of of economic status in the elderly; and the relationships among nutrition, cellular structure, and function in the elderly.

Attempts have been made to stimulate nutrition research in certain important areas. During 1978 and 1979 Requests for Proposals (RFPs), Requests for Applications (RFAs), and program announcements have been issued individually by the Institutes and jointly through the NIH Nutrition Coordinating Committee. As a result, in FY 1980, in addition to continuing support in the above areas, NIH will fund studies on overnutrition and obesity; nutrition in relation to health of the aged and aging processes; human milk bank research; effect of diet on metabolism, structure, composition and blood levels of lipoproteins; nutritional assessment of patients with cancer; in vivo quantification of body nitrogen; nutritional aspects of cancer and its etiology/prevention, treatment, rehabilitation, and training; quantification of changes in body composition in cancer patients; environmental and host factors affecting nutritional requirements; iron deficiency; effects of nutrition on physical and mental development, behavior, physical capability, and work performance; health consequences of different and changing dietary patterns and food habits; and the role of nutrition in the rehabilitation of patients with cancer.

Furthermore, the NIH plans to fund 10 to 12 Clinical Nutrition Research Units in FY 1979 and 1980, the specific objectives being as follows: 1) to create or strengthen foci in biomedical research institutions for multidisciplinary research in clinical nutrition in order to develop new knowledge about specific nutrients in health, human development, and the prevention and treatment of disease; 2) to strengthen training environments in order to improve the education of medical students, house staff, practicing physicians, and paramedical personnel in clinical nutrition; and 3) to enhance patient care and promote good health by focusing attention on clinical nutrition and generating nutritional information for the public. Each Unit will consist of seven components: research with human subjects and populations; laboratory investigations; research training; shared facilities and research services; education programs for medical students, house staff, practicing physicians, and paramedical personnel; nutritional support services; and public

information activities. Thus an active national program in clinical nutrition will be established.

Funding levels for FY 1978, 1979, and 1980 are shown in the following table by Institute.

Biomedical and Behavioral Nutrition Research and Research Training

(in thousands)

	1978 Actual Obligations	1979 Estimate	1980 Estimate
National Cancer Institute.....	$18,198	$26,792	$30,660
Nat'l. Heart, Lung, & Blood Inst....	21,934	23,470	23,880
Nat'l. Institute of Dental Research.	2,019	2,221	2,321
Nat'l. Institute of Arthritis, Metabolism & Digestive Diseases....	22,175	26,201	26,020
Nat'l. Institute of Neurological & Communicative Disorders & Stroke....	1,203	1,516	1,516
Nat'l. Institute of Allergy and Infectious Diseases.....	765	1,115	1,227
Nat'l. Institute of General Medical Sciences.....	2,832	2,468	2,591
Nat'l. Institute of Child Health & Human Development.....	16,292	22,225	21,725
National Eye Institute.....	2,664	3,334	3,334
Nat'l. Institute of Environmental Health Sciences.....	3,534	3,530	3,680
National Institute on Aging.....	1,546	3,148	3,348
Division of Research Resources.....	13,136	13,381	13,353
Total NIH.....	106,298	129,401	133,655

NATIONAL TOXICOLOGY PROGRAM

Question: How are the functions of the Environmental Health Institute, and Cancer Institute, the National Institute for Occupational Safety and Health, and the Food and Drug Administration as well as the Environmental Protection Agency being coordinated in the area of toxicology and environmental programs?

Answer: Because research and regulatory interest in environmental health and environmental problems affecting human health are so pervasive, the agencies involved have been sensitive to the need to coordinate efforts. For five years the Department of Health, Education, and Welfare has had a very active Committee to Coordinate Toxicology and Related Programs (CCTRP). Dr. Rall, of the Environmental Health Sciences Institute, is Chairman of that Committee and has served as Chairman since its organization. The Committee brings together all of the HEW agencies active in toxicology and the environmental health sciences. It has taken an active role in the support of information storage and retrieval programs at the National Library of Medicine and in fostering and promoting interagency coordination and collaboration on research and on emerging and specific environmental health problems such as the PBB incident in Michigan.

A related development which will supplement the efforts of the CCTRP is the National Toxicology Program (NTP). The NTP is a specific effort to plan and coordinate the efforts of four Public Health Service agencies active in the conduct and development of methodology for chemical toxicity tests. As such, it is an effort to make these tests as efficient as possible, and to make the total test effort of the Public Health Service as responsive as possible to the technical needs of regulatory agencies such as the Environmental Protection Agency.

I would like to point out that the Environmental Protection Agency and other regulatory agencies outside the Department, such as the Occupational Safety and Health Administration and the Consumer Product Safety Commission, have observers who participate in the activities of the CCTRP and sit as full members of the Executive Committee of the NTP. The Executive Committee is the governing board for that program.

Question: Please provide the Committee with a progress report on the National Toxicology Program outlining its goals and missions.

Answer: I will be pleased to submit a document describing the goals, objective, structure of the National Toxicology Program and the accomplishments to date in organizing and implementing the program.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

THE NATIONAL TOXICOLOGY PROGRAM

On November 15, 1978, Secretary Califano announced the establishment of the National Toxicology Program. The broad goal of this Program is to strengthen the Department's activities in the testing of chemicals of public health concern, as well as in the development and validation of new and better integrated test methods. Specific goals for the program are:

1) To broaden toxicological characterization of the chemicals being tested.

2) To increase the rate of chemical testing, within the limits of available resources.

3) To develop and begin to validate a series of protocols more appropriate for regulatory needs.

To accomplish these goals the Program was established as a Department-wide effort to provide needed information to regulatory and research agencies and to strengthen the science base. The Program is at present comprised of the relevant activities of the Food and Drug Administration, the National Cancer Institute, the Center for Disease Control/National Institute for Occupational Safety and Health, and the National Institute of Environmental Health Sciences. It is being planned, programmed, and carried out as a coordinated whole under the direction of Dr. David P. Rall who continues to serve as Director, National Institute of Environmental Health Sciences, and for the purpose of this Program reports to the Assistant Secretary for Health.

KEY FEATURES OF THE PROGRAM

1. An Annual Plan.

2. An Executive Committee which reviews and recommends approval of the Annual Plan; it also monitors the Annual Plan.

3. A Toxicology Program Board of Scientific Counselors (a public advisory group), which is responsible for reviewing the scientific merit of the program. The Board is composed of eight non-governmental scientists selected by the Secretary.

4. A Program Director.

The Annual Plan

The Annual Plan includes:

A review of current DHEW research as it relates to toxicology.

Specification of the program activities and resources to be managed by the Program Director:

Current toxicology testing capacity (i.e. dollars, positions, and space) and how that capacity is being utilized.

Amount of test capacity which may be available in the coming year.

Plans for test development and validation of test systems which take into account research opportunities and needs of the field.

The compounds to be tested, the test procedures to be followed, and a schedule for the tests.

The regulatory and scientific opportunities which were considered in the development of the plan.

Recommendations of the Program Director as to the resources needed for the Department's toxicology program capacity. (This section will first be included in the second plan, to be completed by September 1, 1979.)

The Executive Committee

The members of the Committee are:

Commissioner of Food and Drugs, Food and Drug Administration;

Assistant Secretary for Occupational Safety and Health, Department of Labor;

Chairman, Consumer Product Safety Commission;

Administrator, Environmental Protection Agency;

Director, National Institute for Occupational Safety and Health;

Director, National Institutes of Health;

Director, National Cancer Institute;

Director, National Institute of Environmental Health Sciences;

Assistant Secretary for Health, Department of Health, Education, and Welfare (non-voting);

Scientific Director, National Institute of Environmental Health Sciences (consultant);

Director, National Center for Toxicological Research (consultant);

Director, Division of Cancer Cause and Prevention, National Cancer Institute (consultant);

Representative from the Center for Disease Control/National Institute for Occupational Safety and Health (consultant);

Toxicology Program Board of Scientific Counselors

This Board, composed of non-governmental scientists selected by the Secretary, advises the Executive Committee and the Program Director on matters of scientific program content and policy, both present and future, as they relate to the Program. It conducts periodic reviews of the Program and its components in the several participating agencies, and evaluates their scientific merit and the overall-quality of the Program.

The Director of the National Toxicology Program

Prepares the Annual Plan. This includes proposing total resources to be dedicated to the Program by each agency.

Presents the Annual Plan to the Executive Committee.

Transmits the recommended Annual Plan to the Secretary, through the Assistant Secretary for Health, for approval.

Publishes the Program's approved Annual Plan.

Reports to the Executive Committee on progress and problems in implementing the Annual Plan.

Proposes major changes in the approved Annual Plan to the Committee.

Directs the performance of the Program under the plan.

Prepares and issues reports summarizing work in progress, and announcing the results of tests conducted by the Program.

Upon request of the Assistant Secretary for Health makes recommendations to him on agency chemical toxicology testing budget submissions.

Transmits the approved Program Annual Report to the Assistant Secretary for Health and to the Secretary.

OPERATION OF THE PROGRAM

The NCI, NIEHS, NIOSH, and the FDA have dedicated program resources to this Program. When agency resources are identified, memoranda of understanding are prepared and signed by the head of each agency and the National Toxicology Program (NTP) Director. These memoranda:

1. Specify those resources to be devoted to the Program.

2. Identify Program components by organizational title.

3. Identify supporting elements of participant agencies, and their responsibilities (e.g., technical services).

These memoranda are updated upon approval of each Annual Plan to reflect shifts of dedicated resources into and out of the Program.

These memoranda provide that the identified organizational elements in each agency are under the immediate direction of the NTP Director, subject to the concurrence of the agency head.

These memoranda provide that management actions in support of the Program's operations are the responsibility of the contributing agency.

RESOURCES

In its first year of operation, the Program totals approximately $41.0 million drawn from currently available resources, comprised of the contributions shown below:

National Cancer Institute	$21.8 Million
National Institute of Environmental Health Sciences	10.2 Million
Food and Drug Administration	7.0 Million
Center for Disease Control/National Institute for Occupational Safety and Health	2.0 Million

PROGESSS TO DATE

The executive committee has been meeting regularly. It has elected a chairman, Dr. Donald Kennedy, Commissioner of FDA. It has established its operating procedures and ratified a plan of action for implementing the program. Currently it is considering the draft of the first annual plan and a priority list of compounds for full-scale toxicity testing.

The principal operating document of the program is the annual plan. The 1979 cycle is somewhat foreshortened because the fiscal year is almost half gone. The first draft has been completed and is being considered by the executive committee. The plan defines testing and research resources made available by the participating agencies. The plan also establishes applied research goals, drawing upon an earlier exchange of information by working-level scientists.

A test inventory has been compiled by the program staff, and a priority list of 103 chemicals has been approved by the executive committee for long term bioassay. Testing protocols will be broadened to include a full range of toxicities as new compounds are entered on full scale tests. There are currently 147 long-term tests underway mostly for carcinogenicity. Twenty-four tests have been initiated in 1979. Additional tests will be initiated as current ones terminate. New chemicals to be entered on broadened test will depend largely upon ability of participating agencies to reprogram additional funds for program activities, and upon prospects for funding continuity in future years.

Implementation of the program is proceeding in accordance with a timetable established in November, 1978. To date, all critical milestones have been met.

CHEMICAL INFORMATION SYSTEM

Question: Could you please tell us about the joint Chemical Information System with the EPA and NIH?

Answer: The Chemical Information System (CIS) has been developed and maintained by several government agencies, principally the Environmental Protection Agency (EPA) and the National Institutes of Health (NIH). It consists of a collection of computerized chemical data bases together with a family of programs which are used for interactive searching through these data bases. These data bases include files of mass spectra, carbon-13 nuclear magnetic resonance spectra, x-ray diffraction data, and several bibliographic data bases.

The CIS on-line search system is made available for unrestricted use on a fee-for-service basis. The system is of particular value to scientists for a variety of uses such as identification of specific compounds on the basis of structure or name for purposes of reporting in response to regulations such as the Toxic Substances Control Act; identification of potential unknown compounds on the basis of partial analysis or molecular formula; and categorization of compounds by structural characteristics for purposes of studying the correlation of these characteristics to other properties of the compound, such as toxicity or carcinogenicity. These uses are obviously of value to both research scientists and regulatory agencies concerned with toxic chemicals.

Question: Are you supportive of this?

Answer: The NIH supports the concept of a Chemical Information Syytem in which the attributes of chemicals can be stored and retrieved. Closely connected to the CIS system is the development of a Chemical Substances Information Network (CSIN) of which portions of the CIS and other National Library of Medicine (NLM) files such as TOXLINE, CHEMLINE, and the Toxicology Data Bank would be possible nodes in the network. Currently the NLM, which has developed the latter files, is not directly involved in the management or administration of the CSIN. The establishment and operation of this network, which would link relevant information and data sources for on-line multifile searching, will require the cooperation of a number of interested government organizations. The NLM, with other agencies, has supported the development of a prototype on-line Chemical Data Base Directory which will serve as an important entry point in the development of the Chemical Substances Information Network.

The major issues facing the NIH at this time concern the implementation of the Chemical Substances Information Network and the relationship of the CIS to that larger enterprise. Since, as indicated, the National Library of Medicine cannot undertake "administratorship" of the CSIN without additional manpower and fiscal resources, the Environmental Protection Agency is intending to serve in the function of CSIN administrator. The NIH/NLM and the National Toxicology Program will continue to be supportive of the development of the CSIN to the extent possible.

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Question: What are your funding plans in fiscal 1980 as compared to last year?

Answer: The NIH will provide $510,000 for support of the Chemical Information System in fiscal year 1979. Administrative management of the various contracts (development and operations) associated with CIS will be assumed to an increasing extent by the EPA Chemical Information Division, Office of Toxic Substances. It is anticipated that in fiscal year 1980 the NIH will continue to provide a share of the costs of the CIS, approximately $500,000.

CHRONIC PAIN

Question: I have been informed that one of the main reasons why so many patients with chronic pain are not treated more effectively is the virtual lack of knowledge about the mechanisms of pain because in the past, pain research has been neglected by the NIH. Is this true? How much money are you spending on pain research?

Answer: There are many reasons for the serious deficiencies of current pain therapy, but htese can basically be grouped into two major categories: (a) the voids in our knowledge about pain and its mechanisms; and (b) inadequate or improper application of knowledge currently available. A third reason which has been suggested is the obstacle scientists and pharmaceutical companies sometimes feel is put in their paths by the New Drug Application (NDA) process. This is the FDA requirement for marketing rights, frequently time-consuming and expensive to the applicant. Although the NIH is currently supporting pain research at a level of $2.5 million, it is clear that research aimed at elucidating mechanisms of pain and its relief needs to be intensified.

Question: Do we have enough basic and clinical scientists doing pain research in this country?

Answer: With the need for more research in the area of pain, there will undoubtedly need to be more training of basic and clinical scientists to conduct pain research. Further advances in this area will require personnel trained in multidisciplinary approaches to the study of pain. This means, of course, that training support will have to be available to recruit young researchers into this field.

Question: How many training programs do we have that prepare scientists to competently carry out research on pain?

Answer: We currently have several training programs supported by the National Institutes of Health, many of which have implications for the treatment of pain. These include the training programs NIH supports in pharmacology and anesthesiology.

PAIN RESEARCH

Question: Upon the request of the President's Office, you appointed an Interagency Committee on New Therapies for Pain and Discomfort and NINCDS appointed a Panel on Pain, and both groups have made reports. Recently, the NIH and Other Federal agencies sponsored a national conference on pain, which I understand was

highly successful. These three groups have recommended a marked expansion of pain research and research training by the NIH and other Federal agencies. Do you agree with this recommendation, and if so, do you plan to expand your pain research?

Answer: There unquestionably is a need for a significant expansion of pain research and research training by the federal government. It is difficult to estimate the exact dollar amount required. The Interagency Committee has estimated a needed increase of at least $25 million over a five year period in order to underwrite the broad requirements in the control of refractory pain.

It is my hope that NIH will be able to expand its research in this area.

REPORT OF THE INTERAGENCY COMMITTEE

Question: The report of the Interagency Committee contains a list of areas of urgent research needs and recommends mechanisms for achieving these research goals. Do you plan to implement these recommendations? When will you begin?

Answer: Briefly stated, the Interagency Committee recommended the following mechanisms for meeting the research needs in the area of pain:

- Interagency participation and coordination in development and funding of research into pain control.
- National Conference on Pain and Discomfort and Humanitarian Care of the Chronically Ill.
- Transfer of computer-stored information on all Federally-sponsored pain research.
- Increased support for research on pain.
- A study section to review proposals on pain research.
- Suggested mechanisms for support of pain research.

With respect to interagency cooperation in the development of funding of research in pain control, there is clearly a need for a permanent formal working group to coordinate the information on pain research currently conducted by the individual Federal agencies. Such a group would be able to identify gap areas and make recommendations for changes in funding and research emphasis. The Interagency Committee is a prototype of such a group and it has been suggested that a permanent appropriately constituted committee would be useful.

The Conference on Pain, Discomfort and Humanitarian Care, sponsored jointly by the Department of Health, Education and Welfare and the White House was held at the NIH on February 15-16, 1979. Among the many useful outcomes of that conference were the "consensus development" recommendations agreed to by the expert panelists. The NIH-sponsored consensus development program brings together biomedical research scientists, practicing physicians, consumers, and others in an effort to reach general agreement on the efficacy and safety of selected medical technologies.

There is clearly a need to have a complete and accurate listing of all Federally-sponsored pain research. The Division of Research Grants at NIH has its own computerized file which categorizes and stores research. However, with an increased awareness of the need for expanded support of pain research, there may be a concurrent need to institute more detailed categories for support of pain research in order to retrieve useful information in this area.

As stated earlier, NIH provides support for research in pain control and the Director of the Division of Research Grants has agreed to the formation of an Ad-Hoc Study Section to review proposals in the area of pain research until a regularly-constituted group can be established.

Question: One specific recommendation is to increase the level of funding to at least $25 million during the next five years. Do you agree with this recommendation?

Answer: As stated earlier, there is a clear need for expanded support in the area of pain research. NIH, and the other Federal agencies must work toward this goal within the constraints of the budget.

PROGRAM PROJECT GRANTS AND REGIONAL PAIN CENTERS

Question: The Interagency Committee and the NINCDS Panel on Pain as well as the participants in the National Conference have all recommended that all funding mechanisms currently available including program project grants and regional pain centers be used in order to effect significant advances in our knowledge of pain mechanism and therapy.

Do you agree with these recommendations, and will funds be made available for such programs?

What is the current policy of NIH regarding the creation of new research centers or large program projects?

Answer: I agree that all methods of funding should be available to foster advances in our knowledge of the mechanisms and treatment of pain. Both program project grants and regional pain centers are interesting support approaches to this type of research and because such mechanisms would provide a comprehensive perspective of the issues raised in pain control, they may furnish the most appropriate strategies in this particular area.

MENTAL RETARDATION

Question: What action has been taken in response to a letter from Professor Carl Eisdorfer, Chairman of the Department of Psychiatry and Behavioral Sciences, University of Washington? Dr. Eisdorfer presented a series of reasons why the Department's Notice of Proposed Rulemaking concerning persons institutionalized as mentally infirm would seriously impair needed research for older persons with cognitive and emotional disorders.

Answer: The Department has received over one hundred letters concerning the proposed regulations concerning institutionalized mentally disabled persons. The majority of the letters argue that the proposed rules are so strict that they would curb or eliminate important research in such institutionalized persons. The Department is in the process of evaluating each response -- some of them are many pages in length.

After the evaluation is completed, a revised version will be published in the Federal Register with an additional opportunity for comment. Dr. Eisdorder's comments will receive careful and full consideration.

CLINICAL CENTER

Question: How do you allocate research beds in the Clinical Center? Is it true that there are no beds or clinical research facilities for the National Institute on Aging?

Answer: The allocation of research beds in the Clinical Center was originally based on a projection of Institutes' needs. When a new Institute was created, beds were reallocated after a review. As Institute needs change, these allocations may be reviewed and adjusted accordingly. There is no mechanism for formal short-term reassignment of research beds, although beds are "borrowed" depending upon programmatic needs and staff availability.

The National Institute on Aging currently supports a clinical research component at the Gerontology Research Center in Baltimore, Maryland. The facilities include 15 beds used in the Baltimore Longitudinal Study.

The Institute is also actively planning a clinical research program as part of the Bethesda intramural program. This clinical research in neurosciences and nutrition would be a cooperative effort with the National Institute of Mental Health and the National Institute of Neurological and Communicative Disorders and Stroke. When implemented, the program may require some use of Clinical Center facilities.

AGING RESEARCH

Question: Several hearings have been held over the past year on emerging problems associated with an increasing population of aged people in our society. Is NIH's aging research effort commensurate with the magnitude of this emerging issue?

Answer: Our efforts in this area have assumed increasing importance over the last several years, especially with the establishment of the National Institute on Aging. Approximately two percent of the NIH budget is allocated directly to aging research within NIA, but all of our Institutes support research that impacts upon our older population. While this seems a small amount, it actually represents a near doubling of our efforts in the field since 1976. In addition, since aging research is cross-disciplinary, a multitude of collaborative and cooperative efforts have been pursued both within NIH and with other Federal agencies. There are, of course, many areas in the field of aging which have not been explored or which have been looked at only superficially. We would expect to expand into these potentially fruitful areas of research as funds become available.

AGING RESEARCH

Question: Maybe you and Dr. Butler and other Institute Directors could review for the Committee recent advances in and prospects for the life-extending technologies as well as educational information being disseminated to the public.

Answer: Currently most aging research is aimed at studying the aging process to learn how to delay the onset of disease or ease its effects so that people remain healthy and independent for a longer period of time. This research is likely to lead to an increase in life expectancy.

Regarding education of the public, the National Institute on Aging has issued a series of pamphlets to inform medical practitioners and the general public of research advances in aging. Numerous articles on the elderly and on aging research have been published in professional journals, and an article on senility was provided to World Book Encyclopedia. In addition, the holding of workshops and conferences has proved to be an effective way to disseminate information to health professionals and the public. One recent example is a conference held last July on Treatable Brain Disease in the Elderly.

Question: Instead of placing more emphasis on extending life, shouldn't more and more emphasis be in the area of developing a better quality of life?

Answer: Extending the healthy productive years of people's lives is the major goal of the National Institute on Aging. Most of the aging research currently being conducted, both biomedical and behavioral/social, is oriented toward this goal. Biomedical research into the basic mechanisms of aging may some day ease or even eliminate many of the debilitating effects now accompanying old age. Biomedical research is currently leading to new understanding of the factors that promote health in the elderly; for example, we are learning more about proper drug dosage levels and nutritional requirements. Social and behavioral research will contribute to development of support systems which can alleviate specific problems such as social and psychological isolation, extreme depression due to bereavement, and anxiety over such common problems as inability to sleep or concern over impaired physical appearance.

EDUCATIONAL INFORMATION

Question: How are the various programs at NIH relating to the new Office of Health Education in the Office of the Assistant Secretary for Health?

Answer: Each Bureau, Institute and Division produces substantial amounts of health informational materials for the public. Certain of our programs as, for example, the National High Blood Pressure Education Program, include information "campaigns."

Primary responsibility for carrying out these various informational activities rests with the National Institutes of Health. In addition, the NIH has actively cooperated in other Departmental health education initiatives like the Asbestos Awareness Campaign, the Anti-smoking Campaign, Childhood Immunization Program, etc.

The Office of Health Education is kept informed of our health education activities and serves as a point for coordination with other health agencies of our activities in the health education effort.

ZERO-BASED BUDGETING

Question: We have a very thick document that looks like a lot of people put a lot of time and money into, in terms of developing the Zero-Based Budget Book. I would like the opinions of all of the Directors here today as to what benefit, if any, Zero-Based Budgeting works in the area of biomedical research.

Answer: In the area of biomedical research, the zero-based budgeting (ZBB) system has a somewhat limited usefulness. It is very difficult, if not impossible, to rank the programs of one Institute against the programs of another. Programs are not uniformly more scientifically meritorious or more promising in pay-off than other programs, since they are composed of many substantially different, complementary activities. Institutes and their programs are under constant review, and this review is most rigorous during the planning and budgeting process, when an informal evaluation of relative merit occurs.

Imposing a rigid system, such as ZBB, to set priorities for biomedical research is fairly meaningless as a means to determining the wisest allocation of resources. The stability of the research enterprise requires the commitment of funds to all Institutes and programs to a degree. It is only at the margins of these programs that useful resource allocation decisions can be made. Here, there can be clear identification of lowest and highest priorities, and rank ordering aids in the decision-making process.

Following are the opinions of the Institute directors regarding the benefits of Zero-Based Budgeting:

NATIONAL CANCER INSTITUTE

Question: We have a very thick document that looks like a lot of people put a lot of time and money into in terms of developing the zero-based budget book. I would like the opinions of all of the directors here today as to what benefit, if any, zero-based budgeting works in the area of biomedical research.

Answer: With the exception of that situation where there are unlimited resources, priorities must be established for the purposes of program funding and implementation. Every organization has a system or procedure for establishing priorities - the differences between organizations lie primarily in the degree to which the procedure is formalized. ZBB is a highly formalized procedure for the establishment of program priorities. As a management tool, it is applicable and useful in all areas of endeavor, including biomedical research. All programs can benefit from the conceptual approach of building a program from zero-base with the consideration of need, relevance, and priority, and the development of specific program packages for comparison.

The direct benefits of ZBB - that is, using the results of the ZBB exercise as the basis for program operations - vary with the kind of work. ZBB is probably most directly useful in industrial processes or production situations, where the content of the work can be precisely classified and analyzed. In biomedical research, management decisions are based in part on professional judgments and assessments of work content which usually cannot be precisely described or quantified and which can change several times before the work is completed. In biomedical research, therefore, the direct benefits of ZBB as a basis for operations are limited. However, the general benefits from a more formalized assessment of major programs can be very useful to program staff.

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Question: We have a very thick document that looks like a lot of people put a lot of time and money into in terms of developing the Zero-Based Budget book. I would like the opinions of all of the directors here today as to what benefit, if any, zero-based budgeting works in the area of biomedical research.

Answer: The National Heart, Lung, and Blood Institute had, in place, prior to the initiation of zero-base budgeting, a planning process that meets all the criteria of the zero-based budgeting system, i.e., a budget process focused on a comprehensive analysis of objectives and needs; a single process which combines planning and budgeting; and a mechanism which causes managers to evaluate, in detail, the cost-effectiveness of their operations.

The nature of planning, as it is carried out by the National Heart, Lung, and Blood Institute, is a continuous process encompassing activities ranging from the development of policies and strategies at the national level, through the setting of priorities among competing programs, to the establishment of budgets for single programs or projects. It is a yearly cycle characterized by a continuous flow of information from the public, the biomedical

research community, the medical community, other Federal agencies, and non-Federal organizations. The Institute sees its role as coordinating this input and developing it into meritorious programs to be implemented within existing resource constraints.

The NHLBI planning process consists of four distinct but overlapping steps leading to the implementation of new programs or to the expansion, modification or discontinuation of existing programs.

o Step 1. The first step in the process--review, assessment, and consensus--is centered on a series of intensive interactions among the NHLBI program staff, the Institute's scientific advisory committees, and members of the general scientific community. Through an interactive process using workshops, seminars, task forces, and technical working groups, the goals, objectives, and progress of the National Program Plan are reviewed against the state-of-the-science reflected in the published scientific literature and the collective knowledge of the participating scientific experts. During this process, existing research strategies are examined and new ones developed. The major tangible product of this first step in the planning process consists of preliminary lists of recommended program initiatives for the ensuing program years.

o Step 2. The second step in the process--priority setting--is accomplished jointly by the program staff of each of the Institute's categorical divisions and the appropriate advisory committee. During this step, new initiatives are ranked according to the goals and objectives of the National Plan and are rated and ranked by groups of experts in their respective program areas. Based on the advice and recommendations of these experts, NHLBI staff members further develop the more promising initiatives in light of the progress, results, and potential impact of ongoing programs; fiscal and schedule constraints; and program objectives.

The surviving initiatives are further reviewed and approved by the respective advisory committees. The tangible product of this step is a list of categorized and prioritized initiatives.

o Step 3. The third step in the planning process--implementation plan development and review is conducted within the Institute. Each categorical division prepares an implementation plan outlining each new initiative in terms of its scientific and programmatic rationale and justification, funding mechanism, and management and fiscal plan. The Institute Director's office reviews and analyzes each implementation plan and adjusts it to reflect total available resources, congressional mandates and intra-Institute, inter-Institute, and interagency programmatic responsibilities. The adjustments are reviewed and negotiated with each categorical division. The result of this step is the NHLBI Implementation Plan and Program Budget.

o Step 4. The fourth step in the process--National Advisory Council review--provides for direct Council participation in the planning process. Each new program initiative or major program expansion is presented to, and reviewed by, the entire Advisory Council during open session. Council recommendation is solicited and obtained on each initiative, and Council advice on special

areas for emphasis is received. After Advisory Council review, the initiatives and other recommendations resulting from this intense, thorough, and disciplined planning process are ready for implementation.

In concert with the comprehensive process utilized by the Institute the zero-based budgeting process has little to add. Specifically, the procedure and format prescribed by ZBB does not provide the opportunity to adequately discuss Institute programs in sufficient detail for reviewers to make informed decisions nor does it allow for reiteration between program management and decision-makers. Consequently, I can see no benefit in the case of NHLBI to pursue the mechanical exercise of developing a zero-based budget book when a more in depth and scientifically meaningful process is in place.

NATIONAL INSTITUTE OF DENTAL RESEARCH

Question: We have a very thick document that looks like a lot of people put a lot of the time and money into in terms of developing the Zero-Based Budget Book. I would like the opinions of all of the Directors here today as to what benefit, if any, Zero-Based Budgeting works in the area of Biomedical Research.

Answer: I believe the primary benefit of ZBB is derived from reviewing Institute activities from a different perspective. However, in my opinion, subsequent steps in the ZBB process do not permit the objective establishment of priorities for Biomedical research and training.

NATIONAL INSTITUTE OF ARTHRITIS, METABOLISM, AND DIGESTIVE DISEASES

Question: We have a very thick document that looks like a lot of people put a lot of time and money into in terms of developing the Zero-Based Budget book. I would like the opinions of all of the Directors here today as to what benefit, if any, zero-based budgeting works in the area of biomedical research.

Answer: Zero-Based Budgeting is just one of several methods of presenting their budget. We also present it by mechanism of support and by program or disease area. We, at the Institute level, really have no way of knowing which presentation was used to decide on our allowance level. On the other hand, it seems a very complicated and voluminous system to arrive at the decision to hold the budget request to last year's level. The Manpower section is particularly frustrating because although we have repeatedly demonstrated a chronic need for more people to adequately administer our grant and contract programs, this data has never been used at any level to alleviate our problems.

NATIONAL INSTITUTE OF NEUROLOGICAL AND COMMUNICATIVE DISORDERS AND STROKE

Question: We have a very thick document that looks like a lot of people put a lot of time and money into in terms of developing the Zero-based Budget book. I would like the opinions of all of the Directors here today as to what benefit, if any, zero-based budgeting works in the area of biomedical research.

Answer: In my opinion zero-based budgeting--ZBB--is inappropriate for biomedical research. By definition ZBB implies the ability to return annually to a zero base and totally recast priorities and funding. Biomedical research is inherently a long-term endeavor requiring, as an essential ingredient, stability of resources in manpower and budget. Most basic research problems and many clinical investigations and clinical trials take three to five years to accomplish. Research results are not available annually and to attempt to adapt such research to strict ZBB is not realistic. The same principles, namely attention to scientific priorities and program relevance, are achieved within the present framework of peer reviews, advisory council reviews, and program advisory committee reviews, plus the forward plan-implementation plan reviews conducted by each Institute internally and by the NIH as a whole. Over the past several years the ZBB exercises have not seemed to add anything useful or practical to these processes.

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Question: We have a very thick document that looks like a lot of people put a lot time and money into in terms of developing the zero-based Budget Book. I would like the opinions of all the Directors here today as to what benefit, if any, zero-based budgeting works in the area of biomedical research.

Answer: The two-tiered peer review process for grants and contracts is in fact a type of zero-based budgeting since it requires that every project must be re-evaluated and re-justified before funding can continue beyond its initial period. So we have been using this technique at NIH for some time. The problem comes from the consolidation process of trying to fit many different items of research each costing a few million dollars into packages that reflect their importance in the Institutes' overall objectives and needs. We believe much is lost in this consolidation process. Biomedical research cannot be turned on and off through the budget process. It progresses over a period of time based on scientific advances, opportunities, and sometimes luck. A wiser course therefore may be to reduce funding in some areas and increase others as emphases shift rather than think in terms of all or nothing as zero-based budgeting sometimes seems to require.

NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES

Question: We have a very thick document that looks like a lot of people put a lot of time and money into in terms of developing the Zero-based Budget book. I would like the opinions of all of the directors here today as to what benefit, if any, zero-based budgeting works in the area of biomedical research.

Answer: Zero-Based Budgeting or ZBB provides a useful approach for examining resource needs in that it forces decision-makers to carefully scrutinize their budgetary priorities, and to make certain tradeoffs. It is somewhat less useful in the support of basic biomedical research, however, than it might be, say in support of the activities of the Department of Defense. For, we are not dealing with decisions about whether or not to build a new tank or fighter plane, with the funds and the consequences all factored into the decision-making process. We are instead trying to decide

how much biomedical research the nation should support, and the cost-analysis factors are often missing. We do not really know, for example, when funding of a particular research project, or set of projects, designed to elucidate cell structure or protein synthesis will pay off in terms of lives saved or diseases prevented. All we know is that the diagnosis, treatment and prevention of disease are impossible without an adequate knowledge base to work from, and that we must constantly seek new knowledge if cancer, heart disease, diabetes and other diseases are to be conquered. This is further complicated by the fact that someone working on one disease might well come up with a cure for another instead.

NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

Question: We have a very thick document that looks like a lot of people put a lot of time and money into in terms of developing the Zero-Based Budget book. I would like the opinions of all of the Directors here today as to what benefit, if any, Zero-Based Budgeting works in the area of biomedical research.

Answer: At the NICHD, the Zero-Based Budget (ZBB) was particularly valuable as an intra-Institute exercise that required us to make decisions based on determining those programs of highest priority and conversely, identifying those activities that would have to be reduced at lower funding levels. The process was enhanced by the participation of program managers at various levels in the NICHD organization. After the initial effort, however, the preparation of additional materials for submission to the Public Health Service, as well as DHEW, became a heavy administrative burden.

NATIONAL EYE INSTITUTE

Question: We have a very thick document that looks like a lot of people put a lot of time and money into in terms of developing the Zero-Based Budget book. I would like the opinions of all of the directors here today as to what benefit, if any, zero-based budgeting works in the area of biomedical research.

Answer: In my opinion, zero-based budgeting approach to program planning can be a very useful tool for justifying resource allocations. However, it is not realistic to expect it to work in an optimal fashion within the one year budget cycle. One simply cannot effectively evaluate all possible options within this short-time frame. Most advocates of zero-based budgeting within the executive branch recognize this and therefore we are asked to really only concentrate on the last 25 or 30% of the budget. Thus, it becomes much like past incremental systems of budgeting with one significant exception, the ranking of priorities. However, it is often difficult to perform this ranking process as it is very difficult to determine which programs should be prioritized ahead of others when dealing with health problems which are, I am sure, considered of equal importance to Americans affected by particular disorders. This discipline, though, of looking at priorities is probably the main benefit of ZBB.

NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES

Question: We have a very thick document that looks like a lot of people put a lot of time and money into in terms of developing the zero-based budget book. I would like the opinions here today as to what benefit, if any, zero-based budgeting works in the area of biomedical research.

Answer: We have two years experience now in preparation of financial planning documents using the zero-based format. The establishment of standard package formats and definitions for all of NIH this year has been a helpful innovation. However in reviewing the effect of action by organization levels above the National Institutes of Health (the Public Health Service, the Department of Health, Education, and Welfare, and the Office of Management and Budget) it is difficult to perceive the relationship of budget decisions to decision packages which we prepared, ranked and submitted. This experience may demonstrate that it is quite difficult to evaluate using zero-base analysis techniques the relative value of one biomedical research program compared to another or to evaluate the impact of either program cuts or additions.

NATIONAL INSTITUTE ON AGING

Question: We have a very thick document that looks like a lot of people put a lot of time and money into in terms of developing the Zero-based Budget book. I would like the opinions of all of the directors here today as to what benefit, if any, zero-based budgeting works in the area of biomedical research.

Answer: As with any system for developing budget estimates, zero based budgeting has advantages and disadvantages. One of the biggest advantages is the requirement to look at existing programs for opportunities to reallocate resources within the current funding level. Another advantage is the concise way in which add-on funding increments are presented for decision. A major disadvantage is the requirement to rank packages in priority order. Priorities are relative and may change depending on the overall amount of resources available. Ranking all packages assumes that priority setting in biomedical research is much more rational and orderly than it actually is. Another disadvantage is the failure of ZBB to provide on overview of an entire program. It is very good at describing an individual package but it is difficult to obtain a sense of how these packages fit together into a whole program. The danger of burgeoning paperwork is also very real.

NATIONAL LIBRARY OF MEDICINE

Question: We have a very thick document that looks like a lot of people put a lot of time and money into in terms of developing the Zero-Based Budget Book. I would like the opinions of all of the directors here today as to what benefit, if any, Zero-Based Budgeting works in the area of biomedical information dissemination.

Answer: The Zero-Based Budgeting process is useful to the NLM as an additional technique for identification of priorities, but this benefit is offset by the burdensome process and exorbitant volume of paperwork required by the system.

DIVISION OF RESEARCH RESOURCES

Question: We have a very thick document that looks as though a lot of people put a lot of time and money into in terms of developing the zero-based budget book. I would like the opinions of all the Directors here today as to what benefit, if any, zero-based budgeting works in the area of biomedical research.

Answer: Zero-based budgeting (ZBB) is a technique designed to help us answer the questions, "How much should we spend on a particular activity?" and "How should we spend it?" However, when applied to biomedical research, the ZBB technique suffers from two major shortcomings: (1) It is difficult to set a "minimum" level which would be an acceptable effort toward accomplishing research objectives; and (2) It is difficult to set productivity output measures for research programs.

For example, what should be the minimum level of investment toward the objective of applying state-of-the-art technologies to biomedical research as in our Biotechnology Research Program? There are, at this point, many candidate technologies which offer significant benefits to many investigators in biomedical research. Consequently, we must disseminate as widely as possible these many technologies to the best investigators (as rated by the scientific peer review) for their use. Therefore, as we see it, to set a "minimum level" on biomedical research, and particularly on the research, development, and provision of research resources, is to decide how little we can spend on these important activities while still assuring some dissemination of these technologies to the best investigators. This minimum, therefore, can only be a managerial judgment at some increment below the current level.

With regard to research productivity objectives and outputs, we can define broad and optimal objectives but not necessarily minimal or discrete ones. Research productivity is not a linear function of the cost or effort devoted to it; however, ZBB does provide us with a way of comparing the costs of particular levels of the research activity and it provides a form in which we can select alternative research activities.

While there are some features of ZBB that we find useful, we do find that setting a "minimum" level for a research program seems to be arbitrary. Also, we cannot easily measure progress toward research objectives in terms of research activity or performance outputs. In summary, the staff effort in time and money for the ZBB activity measured against its usefulness in research planning and budget allocation is currently not a cost-effective process.

FOGARTY INTERNATIONAL CENTER

Question: We have a very thick document that looks like a lot of people put a lot of time and money into in terms of developing the zero-base budget book. I would like the opinion of all the Directors here today as to what benefit, if any, zero-based budgeting works in the area of biomedical research.

Answer: Although the staff of the Fogarty International Center has put a great deal of time and effort into developing the FIC portion of the zero-based budget, we have seen little, if any, positive results. It may be that officials of higher levels feel that they have a better grasp on budget decisions but from our level it has not assisted us in any way.

OFFICE OF THE DIRECTOR

Question: We have a very thick document that looks like a lot of people put a lot of time and money into in terms of developing the Zero-Based Budget book. I would like the opinions of all of the directors here today as to what benefit, if any, zero-based budgeting works in the area of biomedical research.

Answer: My areas of supervision in the Office of the Director and the Management Fund are different from the Institute organizations. They are support or overhead organizations rather than direct participation in intramural research or managing an extramural biomedical research program. The process of ZBB works rather well in a support organization; it makes you rethink your priorities during every budget cycle. The process is much more difficult to apply against research priorities. I would say, however, even though I did find the dicipline of the process useful, the amount of paper produced was inordinately high in relation to the value of the process.

National Cancer Institute

STATEMENT OF ARTHUR C. UPTON, DIRECTOR

ACCOMPANIED BY:

DONALD S. FREDRICKSON, DIRECTOR, NIH
STEPHEN A. FICCA, BUDGET OFFICER, NCI
NORMAN MANSFIELD, DIRECTOR, DIVISION OF FINANCIAL MANAGEMENT, NIH
KENNETH S. LEVINE, DEPUTY ASSISTANT SECRETARY FOR LEGISLATION, DEPARTMENT OF HEW
WILFORD J. FORBUSH, DEPUTY ASSISTANT SECRETARY, BUDGET DEPARTMENT OF HEW

1979 APPROPRIATION AND 1980 BUDGET REQUEST

Chairman MAGNUSON. It's almost noon.

We would like to get through these Institutes and get out as soon as we can.

So, maybe we can hear from the Cancer Institute.

Dr. Upton?

Dr. UPTON. Thank you, Mr. Chairman.

Chairman MAGNUSON. The budget for the Cancer Institute for 1980 is $936,958,000, and that is $281,000 more than last year.

I am always amazed at the budget recommendations for the Cancer Institute. I remember one time we started out with $4 million for cancer.

So, if you have some comments to make before we get to questions, we will be glad to hear from you. We will include your full statement for the record.

[The statement follows:]

STATEMENT OF ARTHUR C. UPTON

Mr. Chairman and Members of the Committee:

I am pleased to present the budget of the National Cancer Institute for Fiscal Year 1980.

Since my appointment about a year and a half ago, I have conducted an intensive review of every aspect of NCI's activities. As a result, we at the NCI have adopted several operating principles for our comprehensive National Cancer Program. These are: First, strong programs in the prevention and cure of cancer; second, heavy commitment to basic research to clarify the process of carcinogenesis; and third, programs to promote increased use of new knowledge.

Prevention Activities

High among our priorities in research aimed at cancer prevention are studies to identify cancer-causing chemicals in the environment and to protect people against their effects.

In the past year, the NCI's Bioassay Program has eliminated the backlog of reports on tests of some 207 chemicals in rats and mice, which has been previously of concern to you and to me. All the reports have been sent to the regulatory agencies. In all, 102 out of a total of 247 chemicals tested thus far in animals have been found to be carcinogenic under the test conditions. The NCI plans to continue such long-term animal testing as a means to identify other chemicals potentially hazardous to man. The Institute plans also to refine the knowledge necessary for better interpretation of the tests in estimating the risks to man.

Because testing in animals is costly and time-consuming, efforts are in progress to develop rapid and inexpensive laboratory tests of chemicals for cancer-causing potential. Several such short-term experimental methods have been developed, and this year we hope to evaluate their reliability.

The new HEW National Toxicology Program will greatly improve coordination among Federal agencies in identification and regulation of chemical hazards in the environment. The NCI and three other agencies, the National Institute of Environmental Health Sciences, Food and Drug Administration, and National Institute for Occupational Safety and Health, will share the cost, and work under a centralized structure to evaluate the toxicity, including carcinogenicity, of environmental agents.

Epidemiological studies to identify high-risk populations and environmental carcinogens constitute another high-priority line of investigation in our cancer prevention program. These studies, which have pointed to the role of cigarettes, radiation, and occupational factors in causing cancer, are also attempting to sort out the relative importance of diet, drugs, hormones, genetic factors, and atmospheric pollutants in the development of cancer.

A re-evaluation of the contribution of occupational exposure to cancer incidence--from the point of view of prevention--has suggested greater impact than previously suspected. For example, asbestos, a fibrous heat-resistant mineral, has been linked to an exceptionally high rate of lung cancer and other diseases among workers in the shipbuilding and construction industries. In asbestos workers, moreover, the risk of lung cancer is disproportionately increased by cigarette smoking. Because millions of workers have been exposed to this carcinogen, the NCI has organized, on behalf of HEW, an Asbestos Awareness Program to alert exposed populations to the possible hazards of such exposure. In conjunction with this effort, an NCI-led Asbestos Education Task Force has developed relevant educational materials for concerned health professionals.

In relation to the prevention of smoking-induced cancer, NCI has contributed chapters and data to the recent Surgeon General's Report on Smoking and Health. It also has developed and distributed various educational materials, including a Smoking Digest, and a Helping Smokers Quit Kit for use by physicians with patients.

Research on the mechanisms of carcinogenesis is another important approach to cancer prevention. Through this approach, it has been found that certain vitamin A-like chemicals, known as retinoids, have a potential for inhibiting the development of epithelial cancers, such as cancer of the bladder. This has resulted in NCI support for clinical trials to determine the effectiveness of 13-cis-retinoic acid in preventing new lesions of the bladder in persons who have had early bladder cancers removed surgically.

Other laboratory studies with the Rous sarcoma virus of chickens have identified the protein product that is believed to be responsible for transforming the infected cells into cancer cells. This protein is not a part of the virus itself but rather a product coded for by a viral gene. The identification of this transforming protein represents a milestone of far-reaching importance. It promises to explain the molecular mechanism of the cancer change, and it suggests, that such gene products may ultimately be used to develop approaches to preventing, or even treating, cancer.

To advance research on carcinogenesis and cancer prevention, additional epidemiologists, pathologists, and cancer biologists are needed. Recruitment of such scientists is possible as a result of Congressional support for new positions and expert consultants. However, these scientists are in short supply, and we are working on training programs in cooperation with other NIH institutes.

Activities to Increase the Survival of Cancer Patients

Detection of cancer before it has spread is important to successful management of the disease. In research to facilitate early detection, major effort is directed to identifying tumor markers, which may be antigens, enzymes, or hormones produced by tumors. Several such markers have been identified and are being evaluated for their usefulness in early detection.

The ultimate criterion for the successful treatment of cancer is restoration of normal life expectancy and well-being. Striking and dramatic improvements have been made in treating those types of cancer that occur predominantly before middle age, with the result that the overall death rate from cancer under age 45 has continued to fall since 1966.

Much of this improvement results from advances in combined therapy since NCI began its drug development program in 1955. Acute childhood leukemia and advanced Hodgkin's disease are but two of about a dozen types of cancer that used to be invariably fatal but are now frequently curable with drugs alone. The mortality rate from Hodgkin's disease, for example, has decreased 30 percent in the last five years. With the most advanced treatments now available the majority of patients enjoy long-term survival, and a high probability of cure.

These results have helped to establish principles now being applied in clinical trials of chemotherapy for the more common types of cancer in adults. The trials focus on the application of drug treatment in the post-operative period in patients who are known to have a high risk of recurrence. This adjuvant chemotherapy should permit more conservative and less traumatic surgery, in addition to improving survival.

One of our breast cancer studies, now in its fifth year, shows strikingly beneficial results in premenopausal women with advanced cancer. These women, who received adjuvant chemotherapy with a three drug combination called CMF at the time of their initial surgery for breast cancer, have shown an 84 percent reduction in recurrence rate and a 65 percent reduction in mortality, in comparison with women not given adjuvant chemotherapy. Within another year we hope to see a trend in improved national survival rates for women with breast cancer, particularly in those under 50. We look upon this as a major advance of the new National Cancer Program.

Other types of cancer in which the new treatments have produced encouraging results are testicular cancer, a disease of young men, metastatic ovarian cancer, one form of lung cancer, and soft-tissue sarcoma. Clinical trials are under way using combinations of drugs, including several new drugs, surgery, radiation

therapy, and immunotherapy. The trials also include hyperthermia, in which the temperature of cancer cells is raised to increase their rate of destruction.

Increased emphasis is being given to improvement in radiation therapy. The NCI is expanding clinical trials of high-energy radiation therapy using subatomic particles such as fast neutrons. This type of therapy may permit the intensification and more precise localization of the radiation effects in tumor tissues. Contracts to secure additional neutron-irradiation facilities and to conduct clinical trials are scheduled for award toward the end of the year.

Through the cancer control program we are continuing our efforts to alert community physicians to the most recent treatment techniques. Our approaches to the upgrading of cancer treatment include clinical oncology programs for large and small communities, outreach programs associated with the Comprehensive Cancer Centers, and cancer control extensions of the Clinical Cooperative Groups.

The National Cancer Institute is directing increasing attention toward the control of cancer-related pain. It supports studies of the occurrence of pain in cancer patients and multidisciplinary projects for the management of pain.

Nutrition and Cancer

The Diet, Nutrition, and Cancer Program, which the Congress established in 1974, has been expanded and relocated in the Office of the Director, to accelerate and coordinate its various activities throughout the five divisions of the Institute.

Studies are being made of a number of dietary factors suspected of influencing the development of cancer. Research is also being carried out to provide nutritional support during therapy and rehabilitation, since a nutritionally balanced patient has an improved chance of undergoing successful treatment and withstanding the rigors of the disease.

Cancer Centers

The recognition of the Cancer Center of Metropolitan Detroit as a Comprehensive Cancer Center brings to 20 the number of such centers across the United States. In addition, there are 29 clinical centers conducting research and demonstration programs and 19 basic science centers. These centers form a strategic national resource for producing new knowledge and transferring the latest cancer information to people in surrounding communities.

Appropriation Request

Mr. Chairman, the request for the National Cancer Institute for fiscal year 1980 totals $936,958,000. The new request includes $254,513,000 for Cause and Prevention Research; $59,989,000 for Detection and Diagnosis Research; $292,656,000 for Treatment Research; $142,472,000 for Cancer Biology; $67,945,000 for Cancer Centers Support; $37,087,000 for Research Manpower Development; $15,937,000 for Construction; and $66,359,000 for Cancer Control.

I shall be pleased to answer questions and supply additional information desired for the record.

Mr. Chairman, this concludes my statement.

Dr. UPTON. Thank you, Mr. Chairman, Senator Schweiker. I am pleased to present the budget for the National Cancer Institute for fiscal 1980.

Since my appointment a little more than a year and a half ago as Director of the Cancer Institute, in consultation with many advisers from the scientific community, I have conducted an intensive review of all aspects of the Institute's programs; and the conclusions emerging from the review lead us to believe that there is evidence of credible progress over many areas and unprecedented opportunities now in research on prevention, detection, diagnosis, treatment, rehabilitation, and continuing care.

In short, I think that the evidence of anticipated progress which prompted the passage of the National Cancer Act in 1971 is borne out.

OPERATING PRINCIPLES

This is the basis for three major operating principles that we have adopted to guide our plans for the future.

First, that there must be continuing, strong efforts, both in the prevention of cancer and the management of the disease. Second, because the understanding we have of the growth of cells and the the factors regulating the growth of cells is still fragmentary, we must be strongly committed to basic research. Third, we must continue programs to promote increased use of new knowledge.

We are not at the stage where we can lay out a blueprint that will predict when we will have specific answers.

In addition, as a result of our congressional mandate, we have responsibility and must continue efforts to promote the use of new knowledge in the day-to-day struggle against the disease.

In the prevention area, I think it is noteworthy that there is increasing evidence that we are dealing with a potentially preventable process. Cancer need no longer be assumed to occur inevitably as a consequence of advancing age.

On the contrary, there is more and more evidence on the interaction of many factors, some of them inherited, many of them environmental and derived from the air we breathe, social habits such as smoking, and so on.

In addition, we see the disease evolving or unfolding through a succession of systems. There is evidence that we can attack the disease at various stages in its process to abort it or prevent it.

We are beginning to identify the causative factors and the stages which they are at.

Much emphasis must be devoted to epidemiological studies of the human populations, looking at populations for higher risks.

Mention was made of radiation workers, identifying risk factors in their environment. There is good evidence that factors in the environment that cause cancer in humans do so almost invariably in test animals as well.

There are examples in which we first learned about the carcinogenic effects of agents in animals, and later found that they cause cancer in humans.

So, if we learn from this that we can identify cancer-causing chemicals in animal tests, we may be able to take preventative action before the human casualties appear. So another of our strategies of prevention is animal testing.

BIOASSAY TESTING

I am happy to report that the backlog of unfinished tests has been eliminated in the past year. Out of some 247 compounds that we have tested so far, a little over 100 have been found to cause cancer in animals under the test conditions. These include many pesticides, compounds in drugs, cosmetics, and industrial chemicals of various sorts.

I am also pleased to report the initiation of the national toxicology program.

This will link very closely the Cancer Institute's efforts in testing with those with the National Institute of Environmental Health Sciences, and the regulatory agencies.

It is clear that there needs to be very close coordination and communication. The problem is immense. The interpretation of test results must rest on sound scientific principles and sound assessment of needs.

Because the animal tests are so time-consuming and expensive—it now takes about 3 to 5 years to test the compound in animals and requires $300,000 to $500,000 per test—it is critical, in view of the large number of substances to be examined, that we more rapidly develop less expensive tests. We are conducting various efforts in this area.

Again, the linkage with the National Institute of Environmental Health Sciences is critical. This is the most cost-effective effort.

I referred to the fact that there is experimental evidence that we can interfere with the development of cancer after exposure to a test substance but before the disease process becomes irreversible and uncontrollable.

We are now at the stage in which some of the substances that appear to have promise, such as vitamin-A-like material 13-cis-retinoic acid, can be utilized in high-risk populations to see whether it can, in fact, offset some of the exposure to carcinogens that may have occurred in the past.

TREATMENT

In the treatment area, it is very clear now that cancer need not necessarily be considered a death warrant. Advances in the treatment of Hodgkin's disease and leukemias have shown that the proper approach, and the right combination of drugs, can be life-saving in many of the victims.

And this approach, then, of applying vigorous, systematic, well-conceived chemotherapy to cancer is being extended into the solid tumors; and we have evidence for progress there.

One of the most notable examples is Wilms' tumor, cancer arising in the kidney of children. Forty years ago this disease was approached by surgery alone, and the survival rate was about 25 percent.

Twenty years ago radiation was used in addition to surgery. Survival improved to about 40 percent.

More recently, by combining surgery, radiation, and chemotherapy, we are getting survivals in the range of 80 percent.

So, the trick now is to orchestrate all of the tools we possess, and it is quite evident that, because we are dealing with a large family of diseases, not all forms respond similarly to a given approach.

So, much must be done in clinical trials and testing with different drugs, and combinations of drugs.

I'm happy to report that the very promising results we mentioned before with cancer of the breast, the second most common cancer in women in this country, is holding up now 4 years after the beginning of that trial.

The comparison of the women, premenopausal women who receive vigorous chemotherapy right after their mastectomy for the disease, in that group the recurrence rate has diminished some 84 percent, and the mortality rate has diminished some 65 percent, as compared with the controlled population who received mastectomy alone without chemotherapy.

We could go on and mention other examples, in which the judicious use of drugs seems to be having its desired effects.

We would expect these trends, which are now evidence in the experimental mode, to be reflected in the national statistics within the next 5 years, for specific causes, for specific types of cancer.

CANCER CONTROL

We are the only Institute at NIH that has a line item budget for control activities—for demonstration and education activities—and we are intensifying these efforts.

It is noteworthy now that our control program has contributed to improvement in the management of the cancer patients in some 1,900 hospitals throughout the country. This number represents nearly 50 percent of all the community hospitals with 50 beds or more.

At least 35,000 health professionals, physicians, nurses, and allied health personnel, have been involved in efforts funded by our control program.

In recent years, the program has placed increasing emphasis on prevention. We can cite as one example here the effort in the asbestos information campaign; another example, is the stilbestrol task force.

There is an approximate 200-percent increase in the budget for nutrition programs over the last 4 years.

CANCER CENTERS

The recognition of the Cancer Center of Metropolitan Detroit as the 20th comprehensive cancer center brings another major institution into this effort. With the 29 clinical centers and the 19 basic science cancer centers, we have established a large network which constitutes a unique and strategic national resource for producing new knowledge.

Chairman MAGNUSON. Now I'm thinking in terms of the one that I know best, the Hutchinson Center.

Do they communicate with each other?

Dr. UPTON. Yes. The centers are linked together in an association of cancer centers; and through our centers program we are maintaining the cohesion and the coordination, which I think needs to

be intensified. I see the centers as providing a network for prevention efforts, treatment efforts, and control efforts of all sorts.

Chairman MAGNUSON. Some of them get branched out into certain portions of the cancer problem, and then another one goes in another direction, so that if they find something, they can specialize, like the Hutchinson Institute?

Dr. UPTON. Dr. Thomas' outstanding work with marrow transplantation at Hutchinson Center is well known in the country.

Chairman MAGNUSON. Have you got enough money in there to keep those things alive, including the Hutchinson Center?

Dr. UPTON. The projection for cancer centers for fiscal 1980 is virtually the same, as you note, as for 1979. The budget for 1979 calls for $67,832,000; the budget for 1980, $67,945,000. So we are attempting to hold the line even.

Chairman MAGNUSON. So it is approximately the same amount.

Are all of them like the Hutchinson Center? We have, as you know, a great deal of private contributions to that center. Are all of them that way?

Dr. UPTON. Mr. Chairman, this does vary appreciably. I think that in general the Hutchinson Center does receive a greater fraction of its total resources from the private sector than does the average center.

Chairman MAGNUSON. I'm always going to affairs that are raising money for the Hutchinson Center. Hutchinson is busy all the time in getting that money.

But they all don't have that participation, do they?

Dr. UPTON. No.

Chairman MAGNUSON. All of them have some, though, don't they?

Dr. UPTON. They virtually all have some support from non-Federal sources. But the fraction of the total support that is derived from the private sector does vary enormously. The centers are quite heterogeneous, as you mentioned.

CANCER ADVANCES

Chairman MAGNUSON. Yes.

I think you mentioned in the general statement—but what are the greatest advances that we have made in cancer research in the last 10 years? Those that you mentioned in your general report?

Dr. UPTON. I have tried to give the general overview; yes, sir.

I think one can cite specifically advances in various areas, and I would be happy to supply detailed information for the record.

Chairman MAGNUSON. I think we need that.

Dr. UPTON. Yes, sir.

Chairman MAGNUSON. Something specific that has happened.

[The information follows:]

MAJOR ADVANCES IN CANCER RESEARCH IN THE LAST TEN YEARS

Great strides have been made in cancer research in the last decade since 1970. Progress continues to be made virtually daily; however, information and data must be consolidated and proven over time in order to be recognized as a "significant" advance in the struggle against cancer. It is then that we begin to see hopeful and encouraging statistics which indicate that a breakthrough is occurring. Some of the most recent statistics from various areas bear out the claim that, indeed, there is rapid progress continually being made against the many forms of cancer. Some of the most significant advances of the programs supported by the National Cancer Program include:

-- Although cancer incidence and mortality have continued to increase in the 1970's, incidence has risen more rapidly than mortality -- reflecting improvements in treatment and earlier diagnosis.

-- Most, but not all, of the increased incidence of lung cancer is due to cigarette smoking. Today, approximately 85 percent of the deaths due to lung cancer are attributable to smoking. If we subtract the lung cancer deaths related to cigarette smoking, total cancer mortality has been declining overall. It has been steady for men and literally decreasing for women, whereas the incidence of cancer, even when correcting for smoking-related lung cancer, is continuing to rise for all groups. When the data are broken down by age and sex, the trends are quite interesting and we see that even the lung cancer picture is not without some signs of improvement. Both the incidence and mortality rates for lung cancer in men are leveling off or perhaps even decreasing up to age 65. This may be due in part, to the lowered smoking rates among older men, and lower tars and nicotine in modern cigarettes. Also, improvements in the work environment are probably reflected.

-- There are other relatively common cancers that have been decreasing in mortality -- including cancer of the stomach, cervix, uterus and rectum. The incidence of stomach cancer is going down perhaps because of dietary changes, such as the increase in the consumption of fresh or frozen fruits and vegetables. Current research in nutrition is examining the relationship between diet and the various types of cancer.

-- One special case is worth mentioning: cancer of the endometrium (the linining of the uterus). This is a disease in which incidence was reported to be rising rapidly (despite increased hysterectomies), a rise which has been linked to the use of post-menopausal estrogens. Publicity was given to this link through Congressional hearings and publication in the professional literature. Within the year of this publicity, and coincident with FDA requiring warning package inserts, the sales of these materials declined, and the reported incidence of this disease also declined. This has important implications for both direct cancer prevention and for basic research in cancer induction,

telling us that estrogens very likely are late-stage carcinogens or "promoters", and that the results of interfering with the action of a promoter can be seen in a very short time, even though cancer in general has a long latent period -- that is, a long time span between the first exposure and the clinical appearance of the disease.

-- There are also important decreases in cancer incidence and mortality in younger persons -- people under age 45. The decreases have come about, in part, through reduced incidence of breast cancer in younger women, lung cancer in younger men, and the childhood leukemias and Hodgkin's disease. The mortality data also reflect substantial improvements in treatment for the childhood leukemias and Hodgkin's disease. The survival rates for these two diseases have improved significantly since the early 1950's.

All of these examples are, of course, reflections of the results of advances made within the various specific research areas of the National Cancer Program.

Cause and Prevention

In the area of Prevention, great progress has been made. Because prevention of cancer is the ultimate goal of all our efforts, we have increased our activities--and our accomplishments--in identifying causes of cancer and learning how they act. The NCI supports epidemiological studies to provide clues to factors that increase cancer risks, and in turn could lead to preventive measures.

--The NCI Bioassay Program has tested 247 chemicals in rats and mice. In all, 104 out of the total of 247 suspect chemicals were carcinogenic under the test conditions. Long-term animal testing as a means for identifying potential cancer risks will continue.

-- Some 80 chemicals have recently been added to the previous world-wide list of 400 chemicals that are carcinogenic for animals. Among the chemicals identified in the NCI Bioassay Program as having cancer-causing activity in laboratory animals and therefore potentially carcinogenic to humans are: Kepone, the pesticides chlordane and heptachlor, the flame-retardant TRIS; the dry-cleaning chemical perchloroethylene; ethylene dichloride, a source chemical for the production of numerous other chemicals; several hair dye ingredients; and three dyes used in textiles, paper, and leather.

-- Approximately 50 environmental agents have been associated with increased occurrence of cancer in exposed persons, including certain metals, ores, chemicals, asbestos, several drugs, air pollutants, petroleum products, tobacco, and radiation. Many of these agents were associated with occupational exposure. Recent estimates suggest that as much as 20 percent of cancer may be associated with occupational exposure.

-- Intensive efforts are in progress to develop rapid and inexpensive laboratory tests of chemicals for cancer-causing potential. Several such short-term experimental methods have been developed. These include tests for DNA damage, production of mutations, and cell transformation. Some of these tests appear to be more specific for cancer-causing activity than do the bacterial mutagenicity tests, while costing less and taking less time than the lifetime studies in animals used in the bioassay program. Moreover, they can be applied to small specimens of food, water, blood, urine, or other materials, thus greatly enhancing our ability to screen for potential cancer-causing agents.

-- Research on how chemical carcinogens act has led to a number of exciting discoveries. One is the realization that many materials identified as carcinogens actually are pre-carcinogens. They become active only after metabolism within the body to "ultimate" carcinogens, which actually initiate the carcinogenic process. Recent studies have identified the compound thought to be the major ultimate carcinogenic metabolite of benzo(a) pyrene, a polycyclic aromatic hydrocarbon widely found in the environment. It is a potent cancer-causing agent in animals and is thought to be responsible for at least part of the human cancer induced by cigarette smoking.

-- Another discovery is that certain synthetic chemicals related to vitamin A and known as retinoids have a potential for inhibiting the development of epithelial cancers, such as cancer of the bladder. This has resulted in NCI support for clinical trials to determine the effectiveness of 13-cis-retinoic acid in preventing new lesions of the bladder in persons who have had early bladder cancers removed surgically.

-- The potential for prevention of cancer by dietary means is receiving increasing attention. The Diet, Nutrition, and Cancer Program, which the Congress established in 1974, has been expanded and relocated in the Office of the Director to accelerate and coordinate its various activities throughout the five divisions of the Institute. Studies are being made of a number of dietary factors suspected of influencing the development of cancer. These include fiber, fats, food additives, artificial sweeteners, alcohol, nitrates, cooking processes and vitamins and minerals.

Detection and Diagnosis Research

Detection of cancer before it has spread is important to successful treatment of the disease. Detection procedures screen apparently normal population groups to find those individuals with a suspected cancer. Diagnostic procedures establish the exact location and extent of a cancer in order to guide treatment.

Some of the most important advances and encouraging leads in the field of detection and diagnosis of cancer include:

-- The use of X-rays has been greatly improved, particularly since the introduction of new sensitive films and computers into radiologic diagnosis. X-ray images are more detailed and exposure

to radiation has been decreased. Computerized tomography (CT), the production of cross-sectional images of the body, is a major advance and an extremely active field of research and development. It permits location of tumors in a way not previously possible by conventional X-rays, revolutionizing the localization of cancers of the central nervous system. Whole-body CT scanning has considerable promise in the diagnosis and localization of other deep-seated cancers, such as cancer of the pancreas.

-- Research is being emphasized to improve early detection procedures. Major effort is directed toward identifying and purifying biological markers, which may be antigens, enzymes, or hormones produced by cancers. Several such markers have been identified and are being evaluated for their usefulness in early detection.

-- Discovery of the steroid hormone receptor proteins (estrogen-binding proteins) is viewed as another of the significant advances of the past few years. A test for estrogen receptor protein in breast cancer tissue has been developed to determine whether a patient with recurrent breast cancer would respond to treatment with hormones.

-- The NCI is involved in the development of improved flexible fiberoptic endoscopes, instruments to examine inner organs. They are being used to pinpoint the location of cancers of the bowel and lung, and have shown promise in the diagnosis of cancer of the pancreas. Another technique under study is the ultrasonic probe, which can be inserted through endoscopes to examine inner organs of the body and thus facilitate the diagnosis of small cancers.

-- A large screening study of heavy cigarette smokers is evaluating the combined use of sputum cytology and chest X-rays for diagnosis of early lung cancer. Results thus far indicate that cancers can be found when they are small and presumably before they have spread. Lung cancer is so highly malignant, however, that further study is needed to determine whether treatment of these small cancers will lead to cure.

-- NCI programs to demonstrate the detection of early breast cancer and uterine cervical cancer in high-risk populations have screened more than 1 million women.

-- The NCI is continuing research on non-invasive techniques for detecting breast cancer, such as ultrasound, thermography and biological markers. A prototype instrument for making mammograms by ultrasound is being evaluated in clinical studies. A thermographic apparatus is also being evaluated clinically; it produces an absolute temperature digital map recorded on magnetic tape. The data thus obtained provide more detailed information on thermographic patterns than were available previously.

-- The National Cancer Institute also supports projects in instrumentation to facilitate detection and diagnosis. Machines are being developed to help read the many specimens obtained in the Pap test screening for uterine cervical cancer.

A "flow-through system" has been developed in which single cells in a fine stream pass through a laser beam. Computer analysis of Pap test cells under the microscope is another approach being developed to identify cancer cells by pattern recognition techniques.

Treatment Research

Perhaps the greatest advance in cancer treatment in the last ten years has been the realization and proof that cancer survival rates were not going to be significantly increased with refinements in surgical and radiotherapeutic techniques only. What was needed was a form of systemic therapy. By the early 1970's, it was convincingly demonstrated that chemotherapy alone could cure cancer. The most astonishing advancements have come in the treatment of pediatric cancers where we are now able to cure 50% of all children with cancer. This clearly was not the case ten years ago.

The more recent past has seen several significant advances in cancer treatment research. These advances have been in both the preclinical treatment research area through the development of new, anticancer drugs, as well as the clinical treatment area with the high probability of enhancement in survival rates for patients with more common visceral malignancies.

In the preclinical area, increasing emphasis is being placed on the development of second-generation drugs, those drugs which have the same or better effectiveness as the parent compound with less toxicity. Some examples of second-generation drugs which are showing promise include PALA, 2'-deoxycoformycin, thymidine, interferon, AMSA, and AD-32. Several of these drugs have proven effectiveness without the unwelcome side effects of nausea and vomiting. Additionally, clinical trials using tetrahydrocannabinol (THC), the active ingredient in marihuana, to suppress the nausea associated with receiving intravenous antitumor drugs are continuing. The preliminary studies appear positive at this time.

Clinical trials involving chemotherapy, radiotherapy, and surgery were undertaken using the modalities either singly or in combination. Advances have been seen among several types of tumors, including:

-- Breast cancer - clinical trials using chemotherapy after mastectomy have shown a 65% improvement in survival at four years for premenopausal women. In the group of patients at highest risk of recurrence, a 100% improvement in relapse free survival has been noted.

-- Testicular tumors - studies have shown a 75% complete response rate in patients with advanced disease. Most of these patients have been disease free for a long enough period of time to be considered cured.

--Oat cell carcinoma of the lung - early studies have shown a complete response rate in excess of 50%. Studies are also showing

a small fraction of patients alive two years after all treatment is stopped. This is significant since a year ago cancer was fatal in 3 - 6 months from diagnosis.

-- Ovarian - combination chemotherapy has induced complete remissions in patients with advanced disease and many of these patients have demonstrated long term survival.

-- Rhabdomyosarcoma - a combination of chemotherapy, radiotherapy and surgery have shown that 50% of treated patients remain disease free.

-- Hodgkin's disease - 70% of patients with this disease can now be cured.

-- Wilms' tumor - studies over the years have shown increased survival rates with surgery, chemotherapy and radiotherapy. Recent studies have demonstrated that the radiotherapy can be eliminated without a decrease in survival.

-- Leukemia - advances have been shown in both acute lymphocytic leukemia and acute myelocytic leukemia with increases in both the complete remission rate and survival rates.

-- Stomach - systemic therapy with a combination of drugs have yielded surprisingly good response rates with complete remissions now appearing.

-- Osteogenic sarcoma - criteria have been established for predicting the toxicity of high-dose methotrexate that will allow for precise prediction of doses of this very effective treatment. Recent use of adjuvant (post-surgical) chemotherapy has increased the disease-free survival to 60% at five years. In addition, aggressive pursuit and resection of pulmonary metastases has further increased the survival of those patients who relapse so that the overall cure rate in some studies is now estimated to be 70%.

-- Small cell and epidermoid carcinoma of the lung - prior to 1972, no effective therapy was available for this devastating disease (median survival of most patients from diagnosis was 2 months). With appropriately administered chemotherapy, and in some cases radiation therapy, the median survival has increased to approximately one year with 25% of the successfully treated patients living longer than two years.

-- Malignant melanoma - strides have been made in the surgical diagnosis and staging of this disease defining groups of patients at high risk of developing recurrent tumor after surgery alone and, thus, paving the way for drug and immunotherapy adjuvant studies. In 1977, a controlled clinical trial indicated that extensive lymph node dissection, previously a routine medical practice, was unnecessary. Another recent adjuvant study has documented an advantage to patients given chemotherapy with DTIC.

-- Brain tumors - there has been a moderate but definite

improvement in survival of adult patients with malignant brain tumors treated with radiotherapy and chemotherapy after surgery. Such trials followed the observation, made prior to 1971, that nitrosourea derivatives induce tumor regression.

-- Non-Hodgkin's lymphoma - since 1971 studies have shown that the majority of adults with advanced stages of the non-Hodgkin's lymphoma of the diffuse histiocytic variety are curable with the use of newly developed combination chemotherapy.

Cancer Biology

In recent years there have been significant breakthroughs in the development of molecular and genetic tools essential for arriving at an understanding of the basic mechanisms of the cancerous process.

-- It has been found that many kinds of tumors (e.g., breast, prostate, ovarian) are dependent upon hormones for growth. There is a large spectrum of natural hormonal and protein factors in serum that can stimulate or inhibit tumor growth. This has led to the use of hormonal therapies.

-- It has been found that the surface composition, structure, and function of tumor cells is altered considerably compared to normal cells.

-- Some special kinds of malignant cells (e.g., teratocarcinomas) can be programmed to develop normally when established in an embryonic environment. The implications of these findings are far-reaching in terms of the cancer process as well as future development of therapies and treatment.

-- Tumors express many characteristics normally seen in the embryonic state, suggesting similarities between embryonic growth and differentiation and tumor growth and differentiation.

-- The number of genes involved in the cancerous state and their recurring and dominant characteristics are being elucidated through major developments in somatic cell genetics and somatic cell hybridization technology. Many tumor cells, especially malignant tumors, have abnormal chromosomes.

-- There is a complex but largely definable series of events that occur when a benign tumor progresses to the malignant or metastatic state. In blood-borne metastasis, only a small percentage of the malignant cells that enter the bloodstream actually survive to form distant metastasis. Unique model systems are becoming available to study this selective process.

Cancer Centers Support

-- In accordance with another Congressional directive, the National Cancer Institute has recognized 21 Comprehensive Cancer Centers across the United States. The criteria for recognition,

recommended by the National Cancer Advisory Board, include clinical and basic interdisciplinary research; demonstration of the best methods of prevention, diagnosis, treatment and rehabilitation; specialized training programs; and educational and communication programs to accelerate the transfer of new cancer knowledge to practicing physicians and the public.

-- The NCI also supports 29 clinical centers conducting research and demonstration programs and 19 basic science centers conducting research spanning all areas of science important to cancer.

Cancer Control

-- Through the cancer control program, we communicate with community physicians, who are the first to see and treat more than 80 percent of all cancer patients. A variety of networks link community hospitals and physicians with cancer centers or major hospitals. Twenty-five networks have been set up to demonstrate the most effective therapies and other intervention methods for cancer of the breast, head and neck, and leukemia/lymphoma. In addition, we support clinical oncology programs in which primary hospitals work with nearby community hospitals, outreach programs associated with the Comprehensive Cancer Centers, and cancer control extensions of the Clinical Cooperative Groups. Thus, the NCI deals directly or indirectly with 1,900 of the 4,000 community hospitals in the United States that have more than 50 beds and serve about 60 million people. More than 35,000 health professionals have been involved in the programs.

-- The National Cancer Institute is directing increasing attention towards the control of cancer-related pain. It supports studies of the occurrence of pain in cancer patients and multidisciplinary projects for the management of pain.

-- The NCI has established six Centers for Radiological Physics to improve the quality of diagnostic and therapeutic radiology. The radiation monitoring techniques developed in these centers, particularly with respect to mammography equipment, which led to much lower radiation exposures, were made available to local communities through the State Health Departments by means of an interagency agreement with the Bureau of Radiological Health (FDA). The Centers also monitor radiation therapy units funded under National Cancer Institute programs. Most of these units are located in community hospitals.

-- Six community-based cancer-control programs are being supported to test the hypothesis that coordinated intervention with a full range of cancer control techniques can have more impact on the cancer needs of people within large communities than a fragmented approach. Types of cancer to be emphasized by interventions in the community-based programs include breast, colon-rectum, lung, uterine cervix, head, neck and prostate.

PAP TEST

Chairman MAGNUSON. I was out at a Swedish hospital, which is adjoining the Hutchinson Center, when my family was out there, and I asked them, when women come in and get tests, do you give them a Pap test?

And they said, no, not unless they ask for it.

I said, don't you think you ought to do it, regardless? It doesn't cost too much. And I guess they are doing it.

But all over the United States, I think there should be some kind of an idea to give all the women a Pap test. That is, when women go in for an ordinary examination.

Dr. UPTON. Yes, sir. We have stressed that.

Chairman MAGNUSON. I think I remember the cost as being about $6 per test.

Dr. UPTON. That is in the right ball park.

Chairman MAGNUSON. This would eliminate a great number of cancers, wouldn't it, or you would catch them early anyway?

Dr. UPTON. We estimate, I think, about 7,500 deaths this year from cancer of the cervix, and one would suppose that the majority of those are potentially preventable if the Pap test is used widely enough.

But primarily in the disadvantaged sectors of society, where the risk is higher and where access and utilization is smallest, is where this occurs.

So, much of the emphasis in our control program is in the development of demonstration centers and the extension of this important screening modality to those segments of the population.

BUDGET PRIORITIES

Chairman MAGNUSON. Now, let's get down to the priorities again. The funds get tighter and tighter.

What areas in the Cancer Institute are now the highest priorities?

Dr. UPTON. As I emphasized, Mr. Chairman, I think that our goal should be the maintenance of a balanced program, and we must therefore strive to maintain the capability to support the most promising research and a variety of approaches.

I think our priorities then would attempt to identify the best avenues of investigation and support those, in a range of thrusts—the prevention area, diagnosis, and treatment, continuing care.

Chairman MAGNUSON. Do you have any specifics on that? Or have you looked into it?

Dr. UPTON. As Dr. Fredrickson laid out the strategy for adapting to the 5-percent cut, we would adopt the same strategy in the Cancer Institute.

We have developed some tentative adjustments in budget to reflect how we would adapt to a 5-percent cut. It would mean about a 1½-percent reduction in the continuing investigator-initiated research, and about an 8- to 9-percent reduction in our contracts program.

It would involve reductions in training of the magnitude that Dr. Fredrickson indicated and reductions in the intramural budget as well.

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INTERFERON

Chairman MAGNUSON. Now, I'm going to ask this question because I've been asked to. I'm not familiar with this one.

Interferon treatment of advanced cancer patients: Are there any trials on that?

Dr. UPTON. Yes. NCI and the American Cancer Society have supported clinical trials, and the trials are ongoing now.

Chairman MAGNUSON. This is for advanced cancer patients?

Dr. UPTON. Yes.

This is a substance which is shed by virus infected cells which interferes with virus replication and viral infection, but also in some way appears to interfere with the growth of tumor cells, at least in certain experimental systems.

The question now is whether in human patients it will have value in the treatment of cancer. The studies to date are inconclusive, but prompt additional and continuing research is required.

We are expecting to continue clinical investigation of interferon under the support of the National Cancer Institute.

Chairman MAGNUSON. Does it show some promise?

Dr. UPTON. There has been suggestive evidence to date. So I would say there is tentative evidence for progress. It is too early to make a final judgment.

Senator SCHWEIKER. Was it interferon or another substance that was written up recently as possibly changing the characteristics of a malignant tumor to rather normal characteristics?

Dr. UPTON. I'm not aware that interferon has caused tumor cells to revert to normal.

But there has been a great deal of interest in interferon, because from early studies there was the suggestion that it was a relatively nontoxic agent.

I think with more systematic study, there has been some evidence of toxicity. It is a lead that deserves to be explored, and we intend to explore it.

NUTRITION

Senator SCHWEIKER. I think it was another substance that I'm thinking of.

You mentioned nutrition in your statement, and my question is: What are we shooting for? What, in a nutshell, is our objective and goal, and what elements of nutrition are we looking for in cancer patients in treating the disease?

Dr. UPTON. We really have two broad goals in the nutrition program: One is to explore the role of dietary or nutritional factors affecting the risk of developing the disease, and the other is to determine the importance of nutrition in the support of the cancer patient in the course of treatment.

Many patients, as a result of the disease itself, become malnourished, almost to the point of disability.

Some of the treatments themselves cause side effects that interfere with the maintenance of proper nutrition, so that the support of the cancer patient becomes another of our important investigative issues.

Senator SCHWEIKER. What about prevention of cancer through nutrition? I think there has been testimony that 40 percent of the

cancers in men and 60 percent in women were nutrition-related; and I think the committee recommended a substantial fund increase for the diet/nutrition program as a preventative step related to cancer.

Dr. UPTON. Senator Schweiker, I would agree that the role of dietary nutritional factors in the cause of the disease is a very important issue, and we have sought to expand our efforts in that area.

As I mentioned in my opening remarks, over the 4-year period, 1976 to 1980, our budget calls for a 200-percent increase.

Senator SCHWEIKER. From what to what?

Dr. UPTON. The total projection for 1980, including all nutrition-related efforts, is some $30 million. I don't have the comparable figure for 1976 in front of me.

Senator SCHWEIKER. I have $18 million for 1978.

Dr. UPTON. For 1978, the sum is $18 million. For 1976, I don't have the figure right in front of me. I can provide that for the record.

Senator SCHWEIKER. All right. Provide that for the record.

[The information follows:]

NATIONAL CANCER INSTITUTE, NUTRITION RESEARCH

[In thousands]

	NCI Budget Level[1]	Nutrition Research
1976	$5,385	[2] $10,200
1977	6,161	16,100
1978	11,404	18,198
1979 (congressional)	14,101	26,792
1980	16,137	30,660

[1] Does not include related nutrition research in carcinogenesis, tumor biology, epidemiology rehabilitation, and other program areas.
[2] Criteria for total nutrition research not developed until 1977. This estimate represents a comparable level based on the new criteria.

Senator SCHWEIKER. I am sure you are aware of the need to increase utilizing hyperalimentation in the treatment of cancer.

This is taken from the August 16, 1978, report of our committee.

Dr. UPTON. We are well aware of the congressional intent, and are striving to respond to the best of our ability.

In responding, Senator Schweiker, I would not challenge the assertion that this is an important area that deserves intensified study. We are doing the best we can to do such studies.

We have taken a number of initiatives in the past years, in issuing program announcements, inviting additional research proposals of various kinds; we have held workshops; we have planned to solicit proposals for nutrition centers as part of an NIH-wide activity.

There are a number of steps we have taken, which lead me to suppose that the budget projection for 1980 is not unrealistic.

I think we can expect to obligate those funds effectively, and this is another area I would be happy to elaborate on for the record.

Senator SCHWEIKER. Yes, I think we should have that.

[The information follows:]

National Cancer Institute
Activities and Initiatives of the
Diet, Nutrition and Cancer Program

Program Structure, Organization and Management

In fiscal year 1978 the Diet, Nutrition and Cancer Program (DNCP) was reorganized, and administration of the program was transferred from the Division of Cancer Cause and Prevention (DCCP) to the Office of the Director. This transfer of responsibility not only broadened the scope of the program, but also allowed effective integration of the dietary and nutritional elements present in all phases of the National Cancer Program. As program coordinator, Deputy Director of the National Cancer Institute oversees all diet and nutrition activities at NCI, including research funded by both the contract and grant mechanisms as well as dissemination of information on diet and nutrition as they relate to the etiology and prevention of cancer and to the treatment and rehabilitation of the cancer patient.

The program is organized into six elements: etiology, prevention, treatment, rehabilitation, resource development, communications, and professional education and training. The actual direction of nutrition activities, including research, comes from the division administering these program elements, and each division retains responsibility for both funding and day-to-day management of specific nutrition projects. DNCP activities in the areas of communications, resource development and professional education are administered by the Office of the Director (OD). Administrative and management support to the DNCP is provided by both the NCI Research Contracts Branch and the NIH Division of Research Grants. Other support services, such as provision of scientific and technical information, information development and dissemination, arrangement of meetings and workshops, and services of a data coordinating center are provided by a support contractor.

Program Activities

Etiology/Prevention

The prevention of cancer depends, to a great extent, upon understanding its causes. The DNCP, through the Division of Cancer Cause and Prevention, has supported much research directed toward gaining insights into the role of diet and nutrition in the etiology of cancer. Some of this research has taken the form of epidemiologic studies of the dietary habits of populations at different risk levels for developing cancer. For example, the DNCP continues to support studies of two religious groups, the Mormons and the Seventh Day Adventists, who have a lower incidence of a variety of cancer types as well as different dietary habits than the general population in the United States. Through a case control study, the project with the Mormons will attempt to identify the relationship between dietary habits and cancer of the colon. The purpose of the other project is to characterize and compare the

diets of the Seventh Day Adventist vegetarians and non-vegetarians and general population controls with respect to the effects of these diets on cancer incidence rates in the three groups.

Another project is investigating the epidemiologic and nutritional variables (especially vitamin A intake) which may differentiate women with positive or suspicious Pap smears from women with negative Pap smears, and to investigate possible relationships between the development of cervical cancer or dysplasia and vitamin A receptor content or binding in cervical tissue. Similar studies are investigating nutritional habits, demographic characteristics, and diagnostic and histopathologic data in colon cancer patients and in controls, as well as studying hormone profiles and pituitary or testicular responsiveness of healthy men and boys, and prostatic cancer cases in low-risk and high-risk populations. Verification of the epidemiologic link between diet and cancer incidence could one day serve as the basis for making dietary recommendations to the public in cancer prevention programs.

The DNCP is also supporting laboratory investigations of the suggested etiologic factors related to nutrition. These include studies of the chemical and molecular mechanisms of induction of cancers by a variety of dietary constituents such as nitroso compounds, aromatic hydrocarbons, mycotoxins, fiber, fats of varying degrees of saturation, and protein of various types and levels, and by compounds found in the gut such as bile acids, fecal steroids and products produced by the fecal microflora.

A factorially designed study is evaluating the effects of type of protein and level of protein on the induction and progression of spontaneous and chemically-induced tumors in mice. Diets with varying degrees of fat saturation are being studied, and responses to various carcinogens by different strains of animals are also being investigated. Mutagens, carcinogens and other substances in food are being studied for their role in human carcinogenesis.

Therapy

Because many cancer patients experience major nutritional problems, the DNCP has emphasized research into the nutritional aspects of cancer therapy. Anorexia, loss of appetite, and cachexia, a state of emaciation and malnutrition, frequently accompany the disease process and may be exacerbated by therapy. The mechanisms of anorexia and cachexia are being investigated to provide baseline information for a prevention program. The purpose of one multi-institutional study of anorexia in adult and pediatric cancer patients is to document the existence of weight loss, to form hypotheses on the possible causes of anorexia, and to develop nutritional intervention methods to minimize the adverse effects of cancer therapy, increase survival rates, prolong survival times, and improve overall quality of life. More specifically, one investigator is studying the role chemotherapy may play in weight loss due to malabsorption as well as the role of insulin ineffectiveness in cachexia. One study of methods for combatting anorexia is evaluating taste changes in cancer patients, while another is studying the role of learned food aversion. Still

another study is attempting to treat anorexia using techniques of behavior modification.

In other studies, NCI has supported evaluation of the efficacy of innovative nutritional support procedures in the prevention or alleviation of malnutrition in cancer patients. The DNCP supported 19 projects aimed at determining if nutritional support before or during various forms of cancer therapy can mitigate the side effects of such therapy, allow more intensive therapy to be given, or improve the quality of life of cancer patients both during and after therapy. These included three multi-institutional studies to demonstrate that optimal nutritional support in the form of total parenteral nutrition (TPN), used as an adjunct to cancer therapy, is safe and effective in maintaining body weight and returning malnourished cancer patients to nutritional adequacy. Additionally, TPN is being examined to determine its effects on tumor growth and host-tumor response in adult cancer patients. Other studies are being funded to determine when manipulation of the oral diet can be used as adjunct therapy or as a direct means of slowing brain tumor growth.

Rehabilitation

For too many years cancer has been viewed as an acute rapidly terminal disease. In fact, many cancer patients now experience cures or striking remissions which allow them to resume basically normal lives. During the course of treatment, however, their nutritional status is ofen dangerously compromised, and restoring good nutritional status is a vital part of the rehabilitative process. This is especially important in children.

Nutrition research projects oriented to aiding the cancer patient in recovery are funded by the Division of Cancer Control and Rehabilitation. These projects include the development of prostheses which allow for more adequate food intake, digestion, and absorption, as well as projects to determine the best types and routes of nutrient intake during the rehabilitation process. Another project is a motivational program that emphasizes the importance of good nutrition. A multidisciplinary approach to rehabilitation, in which nutrition is part of a range of services, including physical therapy, social services and occupational therapy, is also being tested.

Professional Education and Training

As information on the role of diet and nutrition in the course of cancer is gathered, it must be transmitted to appropriate audiences, including scientific investigators and health professionals dealing with cancer patients. Researchers and clinicians alike must be aware of the dietary and nutritional considerations influencing cancer prevention and treatment, as well as factors that can affect basic research investigations. To make such information available, the National Cancer Institute and the DNCP have sponsored workshops to discuss issues in diet, nutrition and cancer and enhance awareness of these issues.

During fiscal year 1978, nine such workshops were held. For these workshops, NCI selected topics for discussion and convened persons with expertise in various aspects of the topic for an exchange of ideas and viewpoints.

Three workshops were held to discuss dietary components with suspected relationships to cancer. The first of this series reviewed the role of alcohol in the causation of cancer. The second focused on the relationships between fat peroxidation products and cancer etiology. The final workshop in this series dealt with the levels and uses of antioxidants in modern diets and their possible role as tumor inhibitors.

Two workshops were held to discuss aspects of animal experiments for cancer research. One considered research problems posed by current methods of production, distribution and storage of experimental diets for animal studies. In the other, areas of laboratory environmental stress which can affect the results of animal studies were identified and discussed. Along these lines, another workshop focused on what role diet may play in the spontaneous remissions of cancers or in unexpected positive responses to cancer treatments.

Often workshops are held to review nutrition research projects, particularly if information materials may be compiled from the research findings. For example, a workshop was held to review final reports from two DNCP projects in taste assessment. Two other workshops focused on development of methods or procedures to assist clinicians and researchers in their work. One of these workshops discussed the preparation of a handbook of standardized methods for nutritional assessment of human subjects, while still another considered the development of a guidebook for including dietary and anthropometric parameters in cancer epidemiology studies.

In addition to these workshops, NCI co-sponsored a national conference on nutrition and cancer in conjunction with the American Cancer Society. The meeting was held June 29 through July 1, 1978, in Seattle, Washington. The primary emphasis of this meeting was the importance of nutrition intervention in cancer treatment. Anorexia, cachexia and hyperalimentation techniques were discussed, and the need for more information on nutrition for physicians and other members of the health team was emphasized.

The National Cancer Institute recognizes the need for nutrition training by all health professionals dealing with cancer patients, as well as the need for skilled professionals to investigate the roles of diet and nutrition in cancer. Research Career Development Awards, and Young and Academic Investigator Awards are mechanisms by which the NCI has encouraged young investigators to direct their research toward issues in nutrition.

Resource Development

Many of the resources needed by investigators to answer questions about nutrition and cancer are not currently available. To meet these needs the DNCP, through the Office of the Director, is

supporting projects to develop a number of tools and techniques for nutrition and cancer research. For example, in 1978 the DNCP supported the development of a comprehensive Nutrient Data Base/Scientific Dietary Analysis System which can be used in analyzing the nutritional composition of an individual's diet.

Studies to develop or improve techniques for assessing nutritional status and determining nutritional requirements were also initiated with the award of ten projects late in fiscal year 1978. Many of the available techniques for nutritional status assessment are appropriate for populations but are questionable when assessing nutritional status of individuals, particularly cancer patients. Most of these methods have never been tested or validated in cancer patients and several of them are unacceptable to the patients. The Office of the Director is therefore funding projects that should validate and standardize existing techniques for nutritional assessment of cancer patients and projects that will develop more reliable and acceptable methods.

Communications/Information Dissemination

The dissemination of information on the relationship of diet and nutrition to cancer is one of the objectives delineated in the 1974 Amendments to The National Cancer Act of 1971. In fact, valid and useful information on the role of diet and nutrition in cancer etiology or prevention, and in the treatment and rehabilitation of the cancer patient, must be made available to researchers, health care professionals and the lay public if NCI is to meet the Congressional mandate. Determining what knowledge can and should be provided for the layman or health professional is not always a simple matter. Nevertheless, the DNCP is confronting the need and desire for appropriate, reliable information.

The DNCP has generated information useful to the scientific and medical communities as a result of nutrition research supported by the National Cancer Institute. In addition to the preparation of speeches, literature reviews, working papers, and state-of-the-art assessments, the DNCP has evaluated scientific contractor reports for their usefulness and suitability for publication. Five such reports, comprising twelve volumes, were submitted to the National Technical Information Service (NTIS) and are now available from NTIS on request.

NUTRITIONALLY RELATED CANCERS

Senator SCHWEIKER. Let me say that one of the reasons we did get specific was that we are told the National Cancer Insitute testified before the Select Committee on Nutrition and Human Needs that 40 percent of cancers in men and 60 percent in women are nutritionally related.

We would be glad to have that for the record.

Dr. UPTON. Senator Schweiker, I would be happy to provide it for the record.

I would like to comment in relation to the statement that——

Senator SCHWEIKER. Do you take issue with that?

Dr. UPTON. I think that the assertion that 40 percent of the cancers in men are nutrition related and 60 percent in women are nutrition related goes further than I would be prepared to go.

I believe that is not an unreasonable hypothesis, but to put that statement into the record as representing fact, I think, would not be reasonable.

Senator SCHWEIKER. All right. That was the gist of the National Cancer Institute's statement before the Select Committee on Nutrition in 1976.

It well may be subject to scientific challenge.

Dr. UPTON. I would want to qualify that, based on what we know today.

Senator SCHWEIKER. All right.

You mentioned, Doctor, that vitamin A-like material seems beneficial in this area.

My question is just a technical one, I guess: Why vitamin A-like as opposed to vitamin A? Is vitamin A the key here? Why are we talking about vitamin A-like, as opposed to vitamin A? Is there distinction between a vitamin A-like material and vitamin A in terms of treating the cancer?

Dr. UPTON. I think the problem here is one of balancing the therapeutic effectiveness, that is, the ability of the agent to produce the desired biological effect, against unwanted and deleterious side effects.

To my knowledge, the initial experience was done in animals with vitamin A itself, and encouraging results were obtained. But to get the best results required such large doses of vitamin A that the animals developed evidences of vitamin A poisoning, became sick, and suffered as a result of treatment.

The pharmacologists and organic chemists began to experiment with modifications of the vitamin A molecule, and were able to determine that vitamin A-like substances were more effective in producing the desired inhibition of tumor growth, without at the same time causing the toxic side effects.

I think we are just really scratching the surface here. It is quite evident that cells can undergo subtle forms of damage that make them liable to grow out in malignant form, but that outgrowth, that expression of the subtle damage, is subject to modification by hormonal substances, or other factors in the environment.

We know as yet very little about these regulatory factors, and the research with cis-retinoic acids can, I think, be expected to lead to ancillary findings with many other substances that provide a basis for protecting against the outgrowth of cells in the malignant process.

Senator SCHWEIKER. All right, Doctor.

We have several questions to be answered for the record at this point.

[The following questions were not asked at the hearing, but were submitted to the Department for response subsequent to the hearing:]

NUTRITION

Question: Nutrition and the Committee's emphasis on developing a sound research program in this area has led to concerns that you are not doing enough in this area. What are your comments?

Answer: Fiscal Year 1979 is expected to be a fruitful year for the Diet, Nutrition and Cancer Program (DNCP). Many of the research efforts begun in the early stages of the program are ending and results of the experiments are being prepared for publication. From the initial projects supported by the program much baseline information has been obtained which is now being used for the formulation of new research projects in which more specific objectives can be delineated. Problems which may have confounded earlier work can be addressed and minimized with refined experimental approaches and protocols. Nutrition research will maintain its prominent role in NCI research efforts.

In FY 1979, grants will be emphasized as the vehicle for funding research. Unsolicited or investigator-initiated grants will be encouraged. In areas of special program interest, Requests for Applications and General Program Announcements have been released. Young Investigator Awards will be an integral part of the DNCP's grants program as NCI seeks to expand research and practice in the area of nutrition.

In general, contract awards will be limited to support services, data acquisition, management of workshops and conferences, and, in some instances, funding of special programs such as the group of nutritional status projects currently being initiated.

Research projects in specific areas of cancer etiology and prevention are being supported by the DNCP under the jurisdiction of the Division of Cancer Cause and Prevention, which is already encouraging submission of research grant applications in the broad areas of diet and nutrition as these might be related to the etiology and prevention of cancer. Research in this area involves the assessment of the role of nutritive and non-nutritive dietary components as carcinogens, procarcinogens, interactions in carcinogen metabolism (activation, detoxification, and metabolism), and relative hazard levels. The DCCP will also evaluate the evidence from epidemiological, clinical, laboratory and animal studies to develop prevention strategies for testing and validation. Nutritional assessment techniques and procedures developed under other aspects of the program may be incorporated for use in prevention strategies. In addition to funding research grants, contract project plans are being developed to evaluate the effect of specific dietary components on carcinogens in laboratory animals.

All aspects of the DNCP related to active oncologic therapy will be the responsibility of the Division of Cancer Treatment (DCT). Research in this area is directed toward improving the cancer patient's quality of life, lengthening patient survival times, and increasing responsiveness to antineoplastic therapy. The DCT has invited grant applications for clinical and preclinical research in the general areas of anorexia, cachexia metabolism (including etiology and pathogenesis), nutritional supplementation, and the nutritional complications of antineoplastic therapy.

Rehabilitation in cancer is concerned with maintenance of host strength and function, prevention of impairment and the early restoration of functional loss resulting from cancer or its treatment. The Division of Cancer Control and Rehabilitation will be responsible for this element of the DNCP and, as such, is seeking interested investigators to develop scientific nutritional regimens that affect the rehabilitation of cancer patients. Examples of research areas which will be pursued under DCCR include dietary counseling for pediatric patients and their parents, evaluating effectiveness of psychological support as an appetite stimulant, and assessing the consequence of malnutrition in host impairment and its relationship to patient rehabilitation.

The DNCP will continue past efforts such as workshops, symposia and the Research Career Development Awards to increase knowledge and awareness of nutritional factors and to encourage the selection of nutrition as an area of specialization by researchers. In the future, the DNCP will also actively campaign for increased emphasis on nutrition education in schools of medicine and other health professionals. For FY 1979, programs are being made available for the training of individuals in the broad areas of diet and nutrition research as these might relate to cancer. Two programs--Individual Postdoctoral Fellowships and Institutional Training Grants--will continue to provide full-time, long-term support to promising individuals and well qualified institutions through the National Research Service Act.

Several conferences and symposia are being planned for FY 1979. A symposium will be held in the spring to promote interactions between the toxicologist and the nutritionist in the use of properly controlled experimental diets. Another symposium is being planned on the subject of nutrition and immunology. A conference on nutrition education for physicians has been tentatively scheduled for mid 1979.

The Office of the Director will be responsible for funding projects designed to develop resources, techniques and procedures to be used as tools in other projects investigating diet and nutrition in cancer. Ten projects to develop and refine methods of assessing nutritional status are ongoing. Methods for quantifying or measuring specific body pools of nutrients, or nutritionally-important components, are being developed. If findings from the studies of nutritional assessment are promising, more extensive study of the nutritional requirements of healthy persons, as well as those suffering from disease, is contemplated.

The establishment of clinical nutrition research units (CNRU's) at cancer centers around the country is a particularly important new initiative of the DNCP now in the planning stage. The purpose of the CNRU's will be to provide a mechanism whereby the divergent groups now conducting nutrition research as it relates to cancer can come together to address the problem of nutrition as it relates to the causation of cancer.

Another direction the DNCP may pursue will be the investigation of adjunct vitamin therapy for cancer. A thorough investigation of these therapies, upon conclusion, will allow us to make some definitive statements about their value and safety, or lack thereof, and recommendations for future studies.

Much of the past activity of the DNCP has been laying the groundwork for the actual dissemination of information on diet, nutrition and cancer and has contributed to the development of an active information dissemination program.

In addition to publishing a series of documents through the NCI, the National Technical Information Service, or other appropriate vehicles, the DNCP plans an active campaign to publicize the availability of these documents. Letters, announcements in scientific and professional journals, Special Cancer Communications and other approaches will be used to ensure that the information developed not only is available, but is also used. Where appropriate large-scale distribution of the documents will also occur.

Question: In fiscal 1980, how much do you plan to spend on nutrition programs as compared to last year?

Answer: In fiscal 1980, it is estimated that the National Cancer Institute will spend $30.7 million for total nutrition as compared to $26.8 million in fiscal 1979.

CANCER CONTROL

Question: Dr. Upton, could you give us some specific examples of how you think your Cancer Control Program has made an impact?

Answer: Some significant accomplishments of the Cancer Control Program are set forth below:

- Established demonstrations for breast and cervical cancer screening of large, high risk populations.

- Twenty-five demonstration networks have been established that link community hospitals to a primary care hospital which provides oncologic expertise in the treatment of leukemia/lymphoma, head and neck, and breast cancer. Over 8,000 cancer patients have benefited from the expertise provided by these networks.

- Funded first organized Hospice in New Haven, Connecticut. Three (3) projects have been initiated to field test approaches to the hospice concept. These will provide the first scientific evaluation of hospice in the United States.

- A major emphasis program to study or demonstrate pain management for cancer patients has been developed. It is estimated that 40-60% of dying patients have severe pain as their most distressing symptom.

- The Division of Cancer Control and Rehabilitation (DCCR) has played a major role in studying effects of in utero exposure to diethylstilbestrol (DES). It is estimated that 1-2 million exposed daughters can profit from these projects.

- Initiated a patterns-of-care study for radiotherapy. The study design requires a national survey of radiation therapy

practices. All cancer patients receiving such therapy will benefit from this project.

- Established and utilized state-of-the-art consensus development conferences to determine those cancer interventions which would be of use to practitioners of medicine throughout the United States. The emphasis of consensus meetings has been related to an examination of cancer screening on a site-by-site basis, (thyroid, cervical, endometrial, breast, bladder, colo-rectal, lung). The thyroid alert to physicians and the public resulted in the Thyroid State-Of-The-Art Meeting.

- DCCR has developed a major program to systematically study the psychosocial impact of cancer on patients and family. Psychosocial considerations are major components of all rehabilitation cancer control programs.

- DCCR has contributed to cancer control activities in 1,900 community hospitals, representing 47 percent of the 4,000 community hospitals with 50 beds or more in the United States.

- More than 35,000 health professionals have been involved in programs funded by DCCR.

- Created wide-spread awareness and funded multiple programs in cancer rehabilitation.

- Implemented rehabilitation research programs.

- Created wide-spread awareness of need for oncology nursing and funded programs in this area.

- DCCR funded projects have resulted in more than 400 publications and major presentations.

- Initiated asbestos education task force -- which can serve as a model for other cancer prevention problems.

- Expanded cancer control experimental studies in selected areas -- Educational approaches, behavorial modification, transfer methodologies, limited field testing of interventions, limited epidemiologic studies to refine existing information base, and studies of problems in the health care system to assess needed change and impact in cost, manpower, and patterns of care.

- Continue State-Of-The-Art Consensus Development Meetings and other reviews to reduce premature transfer in the control program and by the community.

- Continue expansion of primary prevention programs by demonstration and education programs.

- Continue detection demonstration programs, cervical and breast screening, to planned completion.

- o Upgrade communication and planning with increased support of cancer control activities in cancer centers.

- o Strengthen coordination of cancer control activities at NCI with cancer control at state and local levels.

- o Assessment of manpower resources available to carry out the expanding national interest in cancer control.

- o Expand community programs, because 80% of cancer patients are managed in community hospitals. Limit community based programs to present number until experience is evaluated. Complete review of clinical oncology programs before expansion.

- o Expand pioneering programs in cancer rehabilitation research, pain management, nutritional support, hospice and psychosocial interventions.

- o Provide contractors with guidelines and advice for evaluation methodology.

- o Continue present pattern of funding demonstration programs providing seed money for developing local capabilities and limit demonstration to 3 to 5 years with "Bell Shaped" funding curve.

Question: How much money are you putting in Cancer Control programs out of your total Institute's budget?

Answer: The Cancer Control Program's objectives complement and support other research activities of the National Cancer Institute. For example, control activities play a key role in the reduction of the occurrence of cancer by making practical and effective techniques of reducing exposure to carcinogenic agents available to health professional and the general public Cancer Control also promotes the ready availability and proper application of resources and techniques for treatment which can benefit cancer patients greatly. For these and other important activities carried on through the cancer control program, $69,733,000 is budgeted for FY 1979, and an expenditure of $69,610,000 is planned for FY 1980, or 7.4% of the total NCI budget for both years.

FREDERICK AND BALTIMORE CANCER RESEARCH CENTERS

Question: Dr. Upton, how much money are we spending at the Frederick Cancer Research Center and the Baltimore Center each year?

Answer: A new contract to operate the Frederick Cancer Research Center was recompeted and awarded in September 1977. The fiscal year 1979 estimate is $23.7 million. Little or no expansion will take place in fiscal year 1980. The above estimate does not include an annual cost of approximately $3 million required to fund the interagency agreement with the U.S. Army for provision of physical support services (electricity, sewage, water, and security).

The Baltimore Cancer Research Program cost is estimated to be $7.5 million in both fiscal years 1979 and 1980.

Question: Do you feel as though we are getting our money's worth from each of these programs?

Answer: NCI considers the research programs located at the Frederick Cancer Research Center to be highly productive and meritorious. Major research programs located at the Frederick center include efforts in the areas of chemical carcinogenesis, carcinogenesis bioassay, cancer biology, viral carcinogenesis, and production of experimental anti-cancer drugs. The productivity of the programs is indicated by the fact that 182 scientific publications were published from the Frederick center during the last year. The scientific accomplishments from the Frederick center have contributed to our understanding of the cancer process.

The Baltimore Cancer Research Program is conducting some very important clinical and preclinical research studies and they are particularly recognized for their research efforts in the treatment of adult leukemia. We believe the Baltimore Cancer Research Program is a very valuable integral component of the NCI program.

Question: What are your plans in this area for fiscal year 1980?

Answer: Little or no expansion of the Frederick Cancer Research Center programs is anticipated for fiscal year 1980. The plans for the Baltimore Cancer Research Program are to be maintained at the current level of $7.5 million.

ANIMAL FACILITIES

Question: Do the animal facilities at the NCI meet the National Standards? If not, how much will it cost to bring these facilities into compliance?

Answer: Although the NCI animal facilities meet minimal USDA standards and DHEW standards as recommended in the "DHEW Guide for the Care and Use of Laboratory Animals", not all of the physical plants meet USDA and DHEW recommendations.

Ongoing costs are approximately $1,585,000 for animal procurement, maintenance and support. Upgrading animal care facilities has been $750,000 annually since 1976 and it is projected to continue at that rate. The NCI recently spent $800,000 to renovate 5,000 square feet of space in the Clinical Center for the Division of Cancer Biology and Diagnosis Central Animal Facility. In addition, the construction of a centralized animal research laboratory is estimated at $30,000,000.

During 1976, a plan was initiated to meet USDA and DHEW recommendations. The plan consisted of the following actions:

a) Conduct a survey of the NIH campus of all animal-utilized and support service spaces assigned to NCI.

b) Track animal care costs and assess per diem charges.

c) Evaluate the animal containment and environmental support needs for NCI conducted research.

d) Centralize review of all animal containment and support equipment purchases to establish maximum uniformity and interchangeability.

e) Upgrade equipment.

f) Establish animal care supervisor positions to guide personnel in the care and maintenance of laboratory animals, to coordinate activities, and to implement USDA/DHEW recommendations.

g) Consolidate and centralize NCI animal spaces.

h) Construct a centralized animal research laboratory facility.

The National Cancer Institute is committed not only to comply with USDA/DHEW standards, but is desirous of seeking accreditation from the American Association for the Accreditation of Laboratory Animal Care.

CONSULTANTS

Question: As you may know last year, the committee began to place tough restrictions on the use of consultants within HEW. In essence, we had found that their funding being spent on consultants has increased from less than $100 million to well over $200 million in fiscal year 1979--we restricted this to $194 million. We have now found that the Cancer Institute has not been reporting their use of expert consultants as required by the Committee and the Department. Could you pleas explain to us why this has not been done?

Answer: Prior to the imposition of the $194,000,000 restriction in the Appropriations Act for Fiscal Year 1979, the National Cancer Institute was not required to report expenditures for those experts authorized under Section 404(D)(1) of the Public Health Service Act. Indeed, the National Cancer Institute considered these experts exempt from inclusion in policies governing the use of this category of employees because of nonconformity with the definition of consultant used in Departmental policy statements. After the ceiling on experts and consultants was imposed, the Department reassessed its previous position and decided that the Cancer experts should be included in this category and thus be counted against the ceiling. Subsequent to this decision, the National Cancer Institute has supplied any and all information requested on our experts. Should you so desire, I would be happy to provide the Committee with copies of all reports submitted thus far.

Question: How do you use these "Expert" Consultants?

Answer: Our experts are used to perform work of a specific time limited duration which requires the particular qualifications of the expert involved. Experts are initially appointed for a period of one or two years and, if the need for their expertise continues, we have the option of renewing the original appointment in one year increments. Their duties cover a wide spectrum of administrative and scientific areas of responsibility and we have found them to be an invaluable aid in the accomplishments of our mission.

Question: Isn't this simply another way to get around the personnel ceiling?

Answer: As to whether or not the use of our expert authority circumvents separately imposed personnel ceilings, I can only say that we have never thought of their use in this way. The authorization to hire experts was originally granted by the Cancer Act of 1971 to aid the National Cancer Institute in the rapid expansion of our capabilities to meet the challenges presented by that act. In the intervening years, experience has shown that the use of the expert authority has indeed been a definite asset in keeping pace with rapidly expanding responsibilities and concommitant program growth. We have repeatedly testified to the usefulness of this authority and Congress has, in the past, seen fit to increase the number of experts we can hire under this authority. Amendments passed in 1978 increased our expert/consultant hiring authorization to the 151 level. I believe that our use of experts is entirely consistent with the often repeated Congressional intent to provide the National Cancer Institute with the capability to rapidly hire high caliber people who are or should be exempt from personnel ceilings. Committee reports will show that Congress has made it very explicit as to their intent in this matter. Therefore, I do not consider the use of experts as an attempt to get around the personnel ceiling but rather the proper use of legislative authorization in full compliance with Congressional intent.

CONSULTANT COSTS

Question: A firm called Enviro Control, Inc. receives several million dollars a year from NCI. They've received over $5 million "to administer the Smoking and Health Program." Approximately $2 million went to them for "development management and support to the Diet and Nutrition Program." They received about $1 million for logistics support of NCI workshops. Why must NCI turn to non-Federal personnel to carry out some of its most important programs?

Answer: There are two consultant services contracts with Enviro Control. One is a prime contract for the Smoking and Health Program (NCI contract number NOI-CP-5-5666) which was funded at a level of $5,079,075 in fiscal year 1978. This figure represents the total amount obligated for all activities under this contract in FY 1978. Because this is a prime contract approximately 94% of the obligated amount was expended for direct research performed by

subcontractors under the prime contract. In its zeal to comply with DHEW policy on contracting for consultant services, NCI erroneously identified the entire contract amount as covering administrative costs. Obviously, the bulk of the money obligated under the contract went for research and not administrative support services. This error has been corrected and the NCI FY 1979 Consulting Services Plan will reflect this correction.

The other consulting service contract which was referenced does supply a broad spectrum of administrative, analytical and technical support services for the Diet and Nutrition Program. This contract (NCI contract number NOI-CP6-5759) received $719,000 in FY 1978 and a total of $1,680,000 since its inception in FY 1976. This is considerably less than the $2 million cited for "Development, Management and Support to the Diet and Nutrition Program" and the $1 million for "logistics support". In summary, I regret that the NCI may have partially contributed to the erroneous impression that Enviro Control, Inc. receives several million dollars a year for consulting services from NCI but this is clearly not the case.

The reasons that prompted the decision to contract for needed services rather than create the capability to perform them in-house are different in each of the cases mentioned above.

When the Diet, Nutrition and Cancer Program was mandated in the 1974 amendments to the Cancer Act, the necessary technical, data analysis, data processing and logistics management support were not available in-house. The decision was made that the needs could best be met by a contractor. As the program developed and needs could be better defined and predicted, it became apparent that the range of services required was so broad, the rate of usage was so sporadic and the cost of duplication in-house was so uneconomical that it was decided to continue to use a contractor to provide these kinds of services.

In the case of the Smoking and Health Program Prime Contract, the decision to contract for needed services was made because the project had a discernable end point in the not too distant future also the nature of the skills mix necessary to conduct the program was such that the NCI deemed it inappropriate to augment its staff to meet the need since such individuals would be of only limited use as permanent staff once the program was completed. The prime contract mechanism was chosen because its feasibility had been proven in other research and development applications.

It should also be pointed out that in each of the cases discussed above, NCI does have its own Project Officer who is in charge of overall program direction and contractor guidance. The program is not simply turned over to non-Federal personnel. NCI personnel are ultimately responsible for the program, its conduct and end results. These are NCI programs in all respects.

Question: The report on consultant costs submitted to this Committee on a semiannual basis has identified a number of areas that merit further explanation.

Why is it necessary, for example, to pay more than $2 million to a firm called JRB Associates for "Budgeting and Implementation Support" to the Office of the Director of NCI?

Answer: Since June of 1974, the National Cancer Institute (NCI) has had a contract with JRB Associates identified as "NCI Resources Modeling and Analysis". The total cost over five years for this contract has been $2.023 million. Originally this contract was solely for support in the area of program planning and analysis and was involved with such important problems as manpower projection models - that is, assessing available manpower against required manpower to carry out the National Cancer Program Plan and a review of priority assessment techniques for resource allocation. In 1976 a fiscal projection model was developed as a tool to aid in the development of the NCI Forward Plan and the previous program planning activities were phased out. In 1977 the fiscal projection model was adapted to aid in the formulation and presentation of the Preliminary Budget, Zero Base Budget request to the President, and the President's budget request to Congress. Currently the operating level of the contract is approximately $200,000 annually and no expansion is planned for 1980.

The need for application of an automatic data processing system to handle the ever increasing complexities of the NCI budget was deemed necessary but nonrecurring in terms of the software development. Therefore, the current plans are to train in-house staff to operate this system.

HEALTH EDUCATION

Question: Please give us some specific examples of how your Institute is working with the Center for Disease Control and the Health Education office in the Assistant Secretary for Health program to develop more effective health education material not only in the schools but in the general population as well.

Answer: The NCI's Office of Cancer Communications (OCC) is working with the Office of Health Information and Promotion (OHIP) in the Public Health Service to develop THE HEALTH MESSAGE TESTING SERVICE to pretest television and radio announcements in prefinished form to improve the quality of public service announcement on health. In addition, OCC and OHIHP are promoting among health educators the use of a variety of pretesting techniques to assure public understanding and use of health education materials, e.g., the promotion of new booklet called Readability Testing.

The Division of Cancer Control and Rehabilitation (DCCR) of the National Cancer Institute has had a long association with the Center for Disease Control (CDC), dating back to 1973. At that time, a multi-year Interagency Agreements (approximately four years) was initiated. This agreements provided for (1) development of smoking education activities and teaching materials; (2) continuation of the San Diego community

organization project; (3) carry on and evaluation of techniques developed for smoking education in public schools; (4) evaluation of public education programs and, (5) development of a systematic documentation of accomplishments.

Further areas of cooperation and collaboration:

- o Since 1975 CDC has cooperated with DCCR to provide smoking education and cessation programs for former asbestos workers in Tyler, Texas.

- o In addition, CDC cooperated with DCCR in the development of National Smoking and Health Surveys directed toward determining smoking behavior, attitudes of health professionals, youth, and the general public.

- o In cooperation with DCCR and CDC smoking materials were developed aimed at high risk populations, i.e., youth, pregnant women and high risk occupational groups.

- o For the past two years, CDC has actively participated in the planning for and conduct of consensus meetings that have been sponsored by DCCR. Currently, they are working with DCCR in the planning of a consensus meeting in the areas of school health education, occupational health education, and smoking cessation.

- o Finally, CDC has been an active member of the Asbestos Education Task Force sponsored by DCCR. The purpose of this Task Force is to exchange information about the scale and kind of health problems that can be attributed to the use of asbestos in the past and in the future and to formulate ways in which to deal with both active and potential health problems.

LAETRILE UPDATE

Question: What is the status of your proposed clinical trials program using this controversial substance known as Laetrile? What if anything, has been concluded about Laetrile's alleged cancer curative properties?

Answer: During 1978 the National Cancer Institute initiated and completed a retrospective study of the drug Laetrile (amygdalin). The results of this study were summarized in the New England Journal of Medicine. On September 25, 1978 the Decision Network Committee of the Division of Cancer Treatment met to consider the clinical data provided by this analysis. The recommendation of this committee was to initiate a prospective Phase II (testing for tumor specificity) evaluation of this drug as part of the Division's Drug Development Program. On December 15, 1978 a notice of claimed investigational exemption for a new drug (IND) with the substances DL-Amygdalin (NSC 251222) and D-Amygdalin (NSC 15780) was filed with the Food and Drug Administration. On January 15, 1979 the National Cancer Institute was notified by the Food and Drug Administration that there were questions regarding the Chemistry Section of the document submitted. The NCI staff is responding to these questions. When these issues have been

sufficiently clarified, the National Cancer Institute will proceed with the Phase II evaluation of this drug. It is anticipated that this prospective Phase II study will take approximately one year to complete. No assessment about Laetrile's alleged cancer curative properties can be made at this time.

SAFER CIGARETTE

Question: How much has NCI spent on the development of a "safer" cigarette?

Answer: Through fiscal year 1978, NCI has spent $31.9 million to develop a safer cigarette.

BIRTH CONTROL PILLS AND SKIN CANCER

Question: We have been informed by several groups that it appears that women who use birth control pills may face an increased risk of developing the fatal skin cancer, malignant melanoma. Have you done anything on this and do you have any opinions on this Dr. Upton?

Answer: One study from California has reported an increased risk of malignant melanoma among women taking oral contraceptives. The increased risk was small and not statistically significant. No information was available on other known risk factors for melanoma, including exposure to sunlight. Therefore, the slight increased risk of melanoma among oral contraceptives users may be due to compounding by other variables. To further evaluate this issue, two case-control studies of melanoma are in progress, funded by the National Cancer Institute and the National Institute of Child Health and Human Development (Contraceptive Evaluation Branch).

OCCUPATIONAL CANCER

Question: How may people in the United States have cancer each year, Dr. Upton?

Answer: It is estimated that for 1979 there will be 765,000 new cancer cases.

Question: Of that number, how many can be related to occupational and envornmental factors?

Answer: About 600,000 cases can be related to occupational and environmental factors.

Question: What portion of your budget is devoted to environmental and occupational cancers?

Answer: In fiscal 1980, NCI plans to spend $177,324,000 on environmental health which includes occupational cancers.

OCCUPATIONAL CANCER

Question: Please give us some specific examples of how your program relates with the Environmental Health Sciences Institute and NIOSH and OSHA.

Answer: 1. In 1973, NCI organized and has since maintained a collaborative mechanism via the Interagency Collaborative Group on Environmental Carcinogenesis which interfaces with some 28 agency programs including NIOSH, OSHA and NIEHS.

2. Acting as a focal point, the DCCP's Office of the Scientific Coordiantor for Environmental Carcinogenesis implements the following:

a) Exchange of information on the carcinogenicity of chemicals alerting agencies on newer test results via telephone and submission of technical reports furnished by Carcinogenesis Testing Program.

b) Responds repeatedly to requests from agencies for information on carcinogenicity data on chemicals using NCI information resources, for example:

1) PHS Publication Series No. 149
2) IARC (International Agency for Research on Cancer)
3) Contract Resources - use of NCI/Stanford Research Institute Data Bank on production and exposure of chemicals. Structure and use class studies are useful indicators in nomination and selection of chemicals in the universe of environmental chemicals.

3. DCCP maintains a Chemical Nomination Working Group (CNWG) which nominates chemicals for NCI to be tested which are then sent to the Executive Committee of the National Toxicology Program. NIOSH and OSHA and NIEHS are part of this CNWG with NIOSH and OSHA in regular attendance.

4. NCI/NIOSH Collaborative Program - Since FY 1976 NCI has provided $4.0 million annually to NIOSH for the support of occupational cancer projects which are of mutual interest to NIOSH and NCI. Project and co-project officers are assigned from both agencies. Since the agreement began, some 66 projects have been initiated, 15 have been completed.

5. NCI has for the last few years collaborated with NIEHS in the design and conduct of carcinogenesis testing projects. For quite a few chemicals NIEHS has been doing the subchronic studies which lead to the ultimate design of the chronic toxicity studies, known as carcinogenesis bioassay.

6. Technical Support of OSHA Hearings - Over the last five years, NCI program staff have assigned NIOSH and OSHA at hearings on such chemicals as vinyl chloride, arsenic, and benzene where standards have been set. Testimony has been rendered by NCI staff to support OSHA and NIOSH in these regulatory processes involving standard setting giving the biomedical rationale for such requirements.

7. Assistance on Advisory Committees for OSHA and NIOSH

   a) NCI program staff have been requested by NIOSH and OSHA to serve on their committees. Examples of these are:

      1) NIOSH Workshop on pesticides
      2) NIOSH Program review of projects at Cincinnati, Ohio.
      3) OSHA Advisory Committee on the development of Federal Register documents on the 14 carcinogens in the workplace.
      4) Some NCI Program staff have assisted OSHA in the development of their priniciples, procedures and/or guidelines relating to occupational carciogens.
      5) NCI program staff have recently acted as consultants to the Interagency Regulatory Liaison Group (including OSHA) in the development of their standards for epidemiologic studies.

   b) Conversely, NIOSH and NIEHS staff also participate in NCI advisory and review groups as well as serving together with NCI staff on NIH, HEW or other advisory groups. Examples of these are:

      1) NIOSH presenting their program to the NCI's Occupational Cancer Task Force.
      2) NCI and NIEHS staff serving together on the NIH epidemiology committee.
      3) NCI and NIEHS representatives recently served together on HEW's Diethylstilbesterol (DES) Task Forces.
      4) NCI and NIEHS and NIOSH representatives are currently serving together on the Interagency Task Force on Radiation.
      5) NCI, NIEHS, and NIOSH representatives are currently serving together on numerous committees and subcommittees of the Task Force on Environmental Cancer, Heart and Lung Disease.

8. Review of NIOSH Criteria Documents - NCI/DCCP/Offices of the Scientific Coordinator for Environmental Carcinogenesis has for at least five years, at the request of NIOSH, reviewed and critiqued documents dealing with standards on 48 chemicals. This is a continuing and routine process.

OCCUPATIONAL HAZARDS

Question: We hear more and more about occupational hazards in the workplace as they relate to cancer. Dr. Upton and Dr. Rall, I would appreciate your reviewing with us just what we are doing in this area and what you perceive as the total problem?

Answer: The National Cancer Institute has taken several steps to bolster its program in occupational cancer. (1) An Occupational Cancer Task Force was formed within the Institute to provide an overview of NCI's activities in occupational cancer, to coordinate these activities with other federal agencies and organizations, and to recommend new initiatives to further strengthen our research and control program in this area. (2) Interagency collaboration has been accomplished through an NCI-NIOSH interagency agreement to accommodate epidemiologic and experimental projects of high priority, and through cooperative arrangements which are being developed with the Social Security Administration, National Center for Health Statistics, and other agencies that have national data resources useful for epidemiologic studies of occupational cancer. (3) An Occupational Studies Section has been formed in the Environmental Epidemiology Branch to help identify chemical and physical carcinogens in the workplace. Emphasis is being given to research designed to explain the "hot spots" identified by the county-by-county survey of cancer mortality, to evaluate the effects of industrial exposures that cross plant boundaries into the general environment, and to assess the hazards implicated by the laboratory studies in the Carcinogenesis Testing Program.

In addition, the NCI, through its Cancer Control Program, supports compilation of information about industrially important carcinogens; preparation and distribution of information for workers about occupational cancer; and availability of information about methods of reducing exposure and risk. There is also periodic assessment of the effectiveness of methods of screening or medical surveillance of those who are at high risk and distribution of information to health professionals on occupational cancer risks.

In the United States it is estimated that in 1979, 765,000 individuals will develop cancer. Accumulating evidence suggests that environmental factors contribute to a large protion of these cancers. The fraction of cancer specifically due to occupational exposures is not known, but estimates have been made that depend largely on the number of assumptions one is willing to accept. These estimates range from 1 or 2 percent to over 20 percent -- a wide range reflecting the following problems: (1) only a few industries have been systematically evaluated for carcinogenic risks; (2) the level of cancer risk associated with low-level exposure to known carcinogens is uncertain; (3) the specific carcinogenic substances associated with hazardous processes are often unknown; (4) the numbers of workers exposed during their lifetime to hazardous substances is unknown; (5) the effects of job exposures to carcinogenic agents in laboratory animals are not always clear; and (6) the future impact of the recent proliferation

of new chemicals in the working environment is unknown. As we continue furthering our efforts to obtain the information to fill in the gaps of knowledge relating to the assumptions, it is likely that our estimates of occupational cancer may rise.

Question: Dr. Upton, what percent of your budget is spent on occupational health research?

Answer: In FY 1979, it is estimated that $17.8 million or about 2 percent of the total NCI budget will support occupational health research. In FY 1980, the estimate is $18.1 million which is also about 2 percent of the total budget.

NATIONAL TOXICOLOGY PROGRAM

Question: Is the newly created National Toxicology Program a more effective program at reduced cost?

Answer: The National Toxicology Program (NTP) is potentially more effective and the increased interagency communications thus far promise to reduce costs. The NTP is newly formed, however, and not yet completely implemented. Because many of the experiments last the lifetime of experimental animals, the cost-effectiveness of the NTP will not be measurable for several years.

If the NTP proves effective, it can serve as a model for the development of similar interagency programs involving trans-agency issues.

Question: Are Inter-Institutional (multi-disciplinary) programs of this sort likely to increase in number, and do they offer potential cost savings in the performance of research?

Answer: Inter-Institutional efforts should be useful in focusing and directing research of common interest and concern and, at the same time, offer potential cost savings. Whether such programs are likely to increase in the future may largely depend on the experience that will be gained over the next couple of years with the National Toxicology Program.

Question: How do both of you coordinate your efforts with the Occupational Safety and Health program in the Center for Disease Control? Please give some specific examples.

Answer: We do have considerable interchange and coordination with the National Institute of Occupational Safety & Health. Examples of this coordination include: a) Experimental Carcinogenesis Information needs - NCI staff provides advice to NIOSH relative to the status of occupationally significant chemicals which we are testing. This information is provided upon request or as we become aware of findings which we think will be of interest to that agency; b) Epidemiological Projects - Currently NCI provides on a fiscal basis $350,000 to CDC which monitors the project conducted by Michigan State Department of Health relating to population exposures to PBB (polybrominated biphenyls). This is a continuing effort with our interest or endpoint being probable induction of cancer from exposure to this fire retardant. FDA and NIEHS are involved in this project.

Question: How do you coordinate your efforts with the OSHA program in the Department of Labor?

Answer: NCI coordinates its efforts with OSHA in several different ways. Some examples include: a) Technical Support of OSHA Hearings - Over the last five years, NCI staff has assisted OSHA at hearings on such chemicals as vinyl chloride, arsenic, and benzene. Testimony given by NCI staff has supported OSHA in regulatory processes involving standard setting; b) Assistance on OSHA Advisory Committees - These include the OSHA Advisory Committee on the development of Federal Register documents pertaining to occupational carcinogens as well as various committees established to develop principles, procedures and/or guidelines relating to occupational carcinogens; c) Monograph Preparation - NCI, has collaborated with OSHA for the past several years in the preparation of monographs on a wide spectrum of chemicals which will be useful for OSHA inspectors in instruction and surveillance activities. This effort is part of the education initiatives of the control program geared to preventive medicine in mitigation or elimination of workplace exposures to carcinogens.

Many efforts are carried out jointly between OSHA and the Cancer Control Program through an inter-agency agreement. Examples of the results include pamphlets in the Cancer Alert Series on the health hazards of such materials as asbestos and arsenic, a film on occupational cancer, grants to educate workers on cancer risks and worker education on asbestos. An Asbestos Education Task Force of the Division of Cancer Control and Rehabilitation (DCCR), whose membership includes the OSHA and other agencies and individuals with special knowledge or responsibility, keeps the problems of asbestos exposure under continuing review in order to facilitate the exchange of relevant information.

National Heart, Lung, and Blood Institute

STATEMENT OF ROBERT I. LEVY, DIRECTOR

ACCOMPANIED BY:

DONALD S. FREDRICKSON, DIRECTOR, NIH
JOHN H. REEDER, BUDGET OFFICER, NATIONAL HEART, LUNG, AND BLOOD INSTITUTE
NORMAN D. MANSFIELD, DIRECTOR, DIVISION OF FINANCIAL MANAGEMENT, NIH
KENNETH S. LEVINE, DEPUTY ASSISTANT SECRETARY FOR LEGISLATION
WILFORD J. FORBUSH, DEPUTY ASSISTANT SECRETARY, BUDGET

BUDGET REQUEST

Senator Schweiker. The chairman stepped out for a little while, so I guess we will proceed with Dr. Levy, Director of the National Heart, Lung, and Blood Institute. Your Institute's request for fiscal year 1980 is $507,344,000.

Dr. Levy. Yes, sir.

Senator Schweiker. I have some questions for the record for the Cancer Institute.

OK. Go ahead, Dr. Levy.

Dr. Levy. In view of the time factor, I will put my statement in the record.

Senator Schweiker. Without objection, that is so ordered.

[The statement follows:]

STATEMENT OF ROBERT I. LEVY

Mr. Chairman and Members of the Committee:

It is, once again, a pleasure to appear before this Committee to testify on behalf of the National Heart, Lung, and Blood Institute. Seven years ago the National Heart, Blood Vessel, Lung, and Blood Act of 1972 initiated a comprehensive national effort to reduce the suffering, death and disability caused by cardiovascular, pulmonary and blood disease. Unfortunately, both then and today, heart disease is ranked the foremost cause of death in the United States. For example, in 1976, heart disease alone was responsible for over 700,000 deaths, almost twice those caused by cancer and seven times those which result from accidents. There is, however, reason to believe that our coordinated program focus of research, validation, training, education, demonstration and transfer has significantly impacted on this major national health problem. In recent years, the steady climb of death rates from cardiovascular disease has been reversed. A decline in coronary heart disease (heart attack), the major killer disease, which started in the sixties has accelerated greatly in the seventies. Deaths from cerebrovascular disease (stroke), listed as third amongst the leading causes of death in the United States, are now declining at a rate of more than 3 percent per year. For all cardiovascular diseases the death rates have declined by over 17 percent between 1970 and 1977 and these declines are evident across all age groups. A recent national conference, sponsored by the Institute, substantiated the magnitude of the decline. It was noted there that for heart attack alone, there would have been almost 200,000 more cardiac deaths, this year, had death rates remained at their 1968 level. Such a momentum must be sustained by the support of research if we are to achieve our goal of preventing heart, lung, and blood diseases and thus eliminating them as a threat to the health, life, and economy of our Nation's people.

Economic Costs

Despite the fact that there has been a steady decline in cardiovascular death rates, these diseases account for more than one-third of all potential years of life lost to illness. Cardiovascular diseases rank second only to respiratory disease as the primary reason for visits to physicians. Even more alarming is data from the Social Security Administration which show cardiovascular disorders as the greatest single cause of permanent disability in the United States. Together, heart, lung, and blood vessel diseases contribute the greatest share of the financial burden of illness, constituting about one-fifth of the total economic cost of illness in this country. The combined treatment costs for these disorders were over $24 billion in 1975, amounting to nearly 25 percent of all United States treatment costs. The economic loss due to morbidity was over $17 billion and losses due to early death cost Americans nearly $30 billion. Overall, the economic burden of heart, lung, and blood diseases exceeded $70 billion and accounted for approximately 29 percent of the total U.S. ecomomic cost of illness. In light of these staggering statistics, ways of reducing these costs are presently being studied by the Institute.

Program Strategy

In order to respond to the challenge of reducing not only the morbidity and mortality but also the substantial social, emotional and economic costs, the National Program will continue to pursue all activities in the biomedical continuum: develop new knowledge concerning fundamental aspects of life processes; critically test and evaluate the existing information prior to application through clinical trials; and, translate proven findings to health practice towards the ultimate goal of primary prevention and cost-effective treatment and rehabilitation. For example, in the basic areas, we still continue to search for the cause(s) of arteriosclerosis and hypertension to enable us ultimately to prevent them. In the validation areas, we support multi-center clinical trials; the most familiar being the risk factor intervention trial which ask, "Does aggressive treatment of cardiovascular risk factors decrease cardiovascular risk?" In the translation area, we are moving

actively to translate the research facts we have today into practical application, as well as asking the question, "How can we achieve and maintain health seeking behavior?" Undoubtedly our best known and most successful program in the translation area is one I have discussed with you for the past two years, the National High Blood Pressure Education Program.

Knowledge Acquisition

New knowledge of the structure and functions of the circulating lipoproteins promises to enhance greatly our understanding of the relationships between nutrition, blood levels of cholesterol, and arteriosclerosis. Research advances in the role of higher neural centers in the brain in the regulation and control of blood pressure are of great potential importance. New observations on the importance of coronary artery spasm not only help us to explain some causes of angina, heart attack and sudden death, but also provide us with some new therapeutic objectives for these disorders. The central role of the delicate balance between lung protease-antiprotease activity appears to provide a coherent understanding of the pathogenesis of chronic obstructive lung disease. Isolation and initial characterization of two new human blood transmitted viruses capable of producing hepatitis in non-human primates offers hope of an early breakthrough in our understanding and eventual control of the now most common form of serum hepatitis, the so-called "Non-A, Non-B Hepatitis". Basic studies of the regulation and control of human hemoglobin chain synthesis may provide us with our ultimate treatments of Thalassemia and Sickle Cell Anemia.

Prevention and effective treatment of overt disease depends to a large extent on our being able to detect its early, often asymptomatic stage. The earlier an abnormality or disease is detected, characterized, and measured, the greater is the possibility for an appropriate intervention to reduce, ameliorate or prevent the often dreadful clinical consequences. Recent advances in a number of non-invasive diagnostic methods have taken place. We are currently developing and evaluating non-invasive diagnostic instrumentation and techniques to image small atherosclerotic lesions using ultrasonic methods. Validation of the clinical application of these techniques is currently being made with the carotid and femoral arteries. If the diagnostic accuracy and specificity of these ultrasonic examinations compare favorably with conventional angiographic techniques they can be repeated, without hazard to the patient over time, to evaluate the patient's progress; promising in the future not only safer, easier, less costly diagnosis, but also the ability to assess more rapidly the effectiveness of therapeutic interventions.

Testing and Evaluating

Clinical trials test, in a carefully controlled setting, the efficacy and safety of preventive and therapeutic regimens with the potential to save hundreds of thousands of lives and billions of dollars each year. They are the key to the long and difficult process which converts research findings to clinically applicable regimens. The Aspirin-Myocardial Infarction Study initiated in October 1974, to determine whether daily administration of aspirin to individuals who are survivors of a documented myocardial infarction will result in reduction in mortality, is coming to completion this summer. When the results are "unblinded" we will have sufficient information to make responsible statements on the role of aspirin in the treatment of coronary artery disease.

Two newer clinical trials began their patient recruitment phase this past year; one (the Beta-Blocker Heart Attack Trial or BHAT) is a multi-center study of the efficacy of propranolol in the secondary prevention of heart attack deaths. Preliminary data and clinical evidence suggest that an agent, like propranolol which can block the sympathetic nervous system activity thought to be often involved in precipitating sudden death, could be of lifesaving value to people with coronary heart disease.

Application of Knowledge

Within recent years, the NHLBI has embarked on demonstration and education activities aimed at speeding the translation of proven research findings into practical community application. The National High Blood Pressure Education Program has, in its six years of operation, contributed to the significant increase in national awareness and increased patient visits for high blood pressure and to the greater than 25 percent decline in the stroke death rate. From our success with this program, the Institute is moving more visibly into nutrition education. While nutrition is a field where all the culprits are still to be defined, we cannot afford to wait until all the results are in. We have a legislative mandate to make the public aware of what is known today, what is fact and what is fiction so that our citizens can make their own informed decisions. For now, much of our program focuses on the potential value of nutrition education at the point of purchase. Successful pilot projects have been completed in cafeterias and with vending machines. The "Foods for Health" project, a new pilot nutrition education research program designed to help consumers make informed choices at the supermarket, was launched, this fall, in cooperation with Giant Foods, Inc.

Knowledge Assessment and Transfer

The transfer of new knowledge into medical practice is a fundamental mission of NHLBI. To this end, the Institute has convened a series of conferences and workshops and has established task forces to determine priorities and the most feasible mechanisms for the clinical application of technologies derived from basic research. Programs have also been supported to determine the impact these technologies have or may have on the health care delivery system.

A transfer program in the blood area is designed to evaluate and make recommendations on present modes of therapy for managing patients with Sickle Cell Disease during pregnancy. The use of prophylactic blood transfusions in the treatment of such patients was initiated in the mid sixties. This technique has gained medical acceptance in some circles but there has been considerable speculation regarding its potential value as a therapy. It is time to make informed conclusions on such issues.

Training and Manpower Development

A continuous flow of new research trainees is vital to the continued health of our research programs. Newly trained scientists and physicians are needed to respond to the expanded and diversified activities of the required research approaches. Declines in the number of new research trainees, especially physicians, over the past several years is of concern. The Institute continues to give top priority to the award of new individual and institutional research fellowships.

This year, the Institute has initiated a Preventive Cardiology Academic Award. The main objectives of this award are to: encourage the development of a quality preventive cardiology curriculum that will attract outstanding students to both preventive cardiology research and medical practice.

In conclusion, Mr. Chairman, I have provided some recent accomplishments and outlined the continuing program emphasis toward the prevention of heart, lung, and blood disease. We have chosen just a few examples of our many programs and I would be happy to supply additional information for the record.

The proposed budget for the National Heart, Lung, and Blood Institute for 1980 is $507,344,000.

NAME: Robert I. Levy, M. D.

POSITION: Director, National Heart, Lung, and Blood Institute

BIRTHPLACE AND DATE: Bronx, New York - May 3, 1937

MARITAL STATUS: Married, 4 children

EDUCATION: June 1953 - Graduated from Bronx High School of Science;
1957 - B. A., Cornell University - highest honors and distinction in Zoology;
1961 - M. D., Yale University - cum laude

EXPERIENCE:

1961 - 1962	Intern in Medicine, Yale - New Haven Medical Center, New Haven
1962 - 1963	Assistant Resident in Medicine, Yale - New Haven Medical Center
1963 - 1966	Clinical Associate, Section on Molecular Diseases
1965 - 1966	Chief Resident, National Heart Institute
1965 - present	Attending Physician, Molecular Disease Branch
1966 - 1968	Attending Physician, Georgetown University Medical Division, District of Columbia General Hospital, Washington, D. C.
1966 - present	Head, Section on Lipoprotein Metabolism and Intervention, Molecular Disease Branch
1969 - 1973	Chief, Clinical Service, Molecular Disease Branch
1970 - 1974	Chief, Lipid Metabolism Branch, DHVD
1973 - 1975	Director, Division of Heart & Vascular Diseases
1975 - present	Director, National Heart, Lung, and Blood Institute
1975 - present	Coordinator for cardiovascular portion of US/USSR Agreement in Health and Medical Sciences
1975 - present	Chairman, National High Blood Pressure Education Program Coordinating Committee
1975 - present	Chairman, Interagency Technical Committee
1978 - present	Member, Advisory Council on Education for Health, Clearinghouse on Corporate Social Responsibility
1978 - present	Panel member of the WHO Advisory Panel on Cardiovascular Disease (World Health Organization)

ASSOCIATION MEMBERSHIPS: American Society for Clinical Investigation; American Institute of Nutrition; American Federation for Clinical Research; American Heart Association Council on Arteriosclerosis; New York Academy of Sciences; American Society for Clinical Nutrition; American College of Cardiology; American Society for Clinical Pharmacology and Therapeutics.

SPECIAL AWARDS, CITATIONS, OR PUBLICATIONS: Kees Prize Research Thesis, Yale University, 1961; Alpha Epsilon Delta (premedical); Alpha Omega Alpha; Phi Beta Kappa; Sigma Xi; Arthur Flemming Award, 1975; DHEW Superior Service Award, 1975; Author or Co-Author of approximately 200 publications; Editorial Board, Journal of Lipid Research, Circulation, and Dialogues in Nutrition; Humanitarian Award, Associated Health Foundation, 1976.

DECLINE OF CARDIOVASCULAR MORTALITY

Dr. LEVY. I am delighted to appear here before you with some good news in this year of austerity, Senator Schweiker.

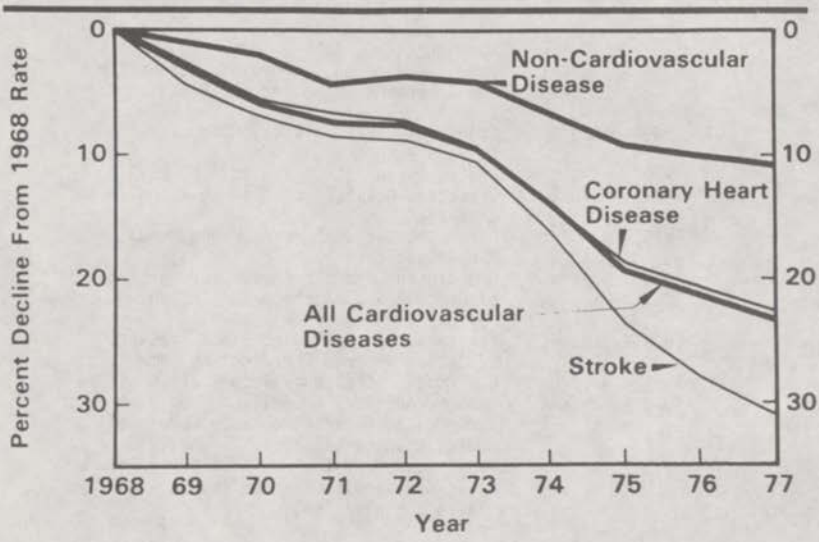
We have reason to believe that our research strategy, a strategy that you and the committee have so vigorously supported, is paying dividends.

We have previously discussed the decline in cardiovascular mortality before this committee.

We believe this graph helps portray its magnitude, the precipitous nature of the decline over the last 10 years, which is interestingly, temporarily strikingly accentuated after the 1972 passage of the Heart, Lung, and Blood Act.

[The chart follows:]

Trends in Cardiovascular Disease and Non-Cardiovascular Disease: Decline by Age-Adjusted Death Rates, 1968-1977.



Dr. LEVY. The mortality rate decline since 1968 is 23 percent. Three months ago, we hosted an international conference at the Institute to look at the decline. The first conclusion of the conference was that the decline was valid. It was not an artifact nor was it due to a misclassification of disease.

It was real.

The second conclusion was that this decline was unique to the United States. Its magnitude and direction was not seen in other countries.

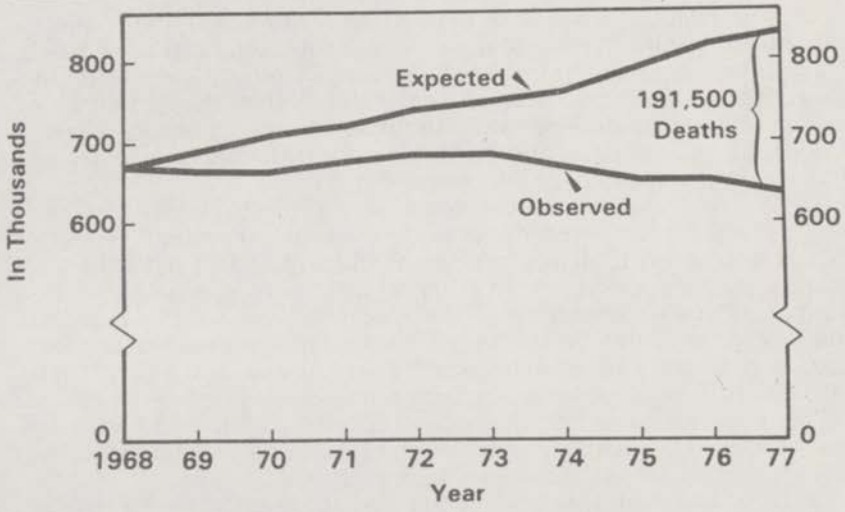
Thirdly, as to the cause of the decline, we could point to risk factor identification, and better public attention to risk factors due to epidemiological research, like that in Framingham, as well as

improved treatment and improved diagnostic capabilities. The exact contribution to the decline, of prevention as opposed to treatment, remains to be determined.

In the next figure, one sees the magnitude of the decline as it has occurred since 1968.

[The chart follows:]

Coronary Heart Disease Deaths, 1968 to 1977: Expected Deaths Based on 1968 Mortality Rates Compared With Observed Deaths.



DEVELOPMENT OF NEW KNOWLEDGE

Dr. LEVY. If we take the death rate that existed in 1968 and project it as existing for the next 10 years, we see that our biostatisticians would have expected that in 1977, there would have been almost 200,000 more heart attack deaths. If we extend this same calculation to all cardiovascular diseases, that is, the event rates in 1968 still applied in 1977, we would have expected some 311,000 more cardiovascular deaths in 1977; and, Senator Schweiker, it is really not necessary to point out that this represents almost as many lives saved in 1977 from cardiovascular diseases as lives lost from cancer each year.

We have reason to believe that the decline will continue.

In new knowledge development this year, we have seen the demonstration of the importance of coronary artery spasm, as a cause of heart attack, angina, and sudden death. This helps us better to understand these problems and suggests new forms of therapy.

We have seen the practical use in man of a new potent oral antihypertensive drug. This drug is specifically geared to block

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angiotensin II, the potent body-made vasoconstrictor hormone that is felt to be the final link in hypertension.

We have seen further confirmation of the fact that chronic bronchitis and emphysema is caused by the lack of a delicate balance between enzymes capable of breaking down the lung tissue, and enzymes capable of breaking down these destructive enzymes.

We have seen the transmission in primates of human blood borne viruses felt to be the likely cause of non-A, non-B hepatitis. This type of hepatitis is presently believed to constitute over 90 percent of all serum hepatitis. Isolation of the viruses promises speedy development of tests to detect and prevent this problem.

CLINICAL TRIALS

Mr. Chairman, I have come before this committee many times to talk about clinical trials and, as you know, our Institute has a heavy investment in clinical trials, some $60 million each year. I've talked about the fact that clinical trials have the potential of saving billions of dollars, and hundreds of thousands of lives. I would like to highlight one particular clinical trial this year, one that has been evaluated, having ended in 1975.

In 1975, we finished the coronary drug project. It was a clinical trial lasting for 13 years, designed to evaluate the effectiveness of cholesterol lowering drugs, and involving over 8,000 patients with heart disease. There were five drugs that were evaluated in this study, and at the conclusion of the study in 1975, we reported that none of these drugs had lowered cholesterol, prevented reinfarction, or prevented heart attack and heart attack death in patients with existing heart disease. In fact, many had serious side effects.

This year, we have had the opportunity to go back and see what has happened to medical practice since the end of that trial and, Mr. Chairman, let me focus on just one drug.

In 1975, the year the trial ended and its results were reported, clofibrate was among the 100 most-used drugs in this country.

Approximately 900,000 Americans were taking that drug. For each patient, the drug costs 30 cents a day, or about $110 a year. We estimated that there was between $95 and $100 million spent by the American consumer on this drug in 1975.

There has been a 55-percent decline in the use of that drug in 1978, compared to 1975. Looking at 1977, we see that the amount of money spent annually for this drug, looking at the National Disease and Therapeutic Index, has declined by some $48 million. Senator Schweiker, the entire 13-year trial to test all these drugs cost us $40 million. So, we have saved the consumer in 1 year, for this one drug, more than the entire cost of the clinical trial.

NATIONAL HIGH BLOOD PRESSURE EDUCATION PROGRAM

In the translation area, our national high blood pressure education program continues to move forward. Union and management are working together in bringing high blood pressure control into the work setting. We have seen an increased involvement of minority groups, especially in blacks, a group in which hypertension is relatively much more frequent.

We have seen a tremendous increase in patient visits for hypertension, up over 50 percent since 1972—a tremendous increase in awareness. In terms of treatment, only about 10 percent of our entire population with high blood pressure, some 3 million Americans were under effective blood pressure control back in 1972. In 1979 we now estimate this to be somewhere between 10 and 15 million Americans, again a tremendous increase.

Senator Schweiker, all these gains, and many others that time precludes detailing, suggest that we can sustain the momentum of decline of the 1970's into the 1980's; that today's research is tomorrow's practical health care, and is capable of saving many lives and many dollars.

STATEWIDE HYPERTENSION CONTROL PROGRAM

Senator SCHWEIKER. All right. I think they are significant advances, and proof positive of cost effectiveness in biomedical research.

So, I am glad you did highlight that.

Last year, the committee, in its report, recommended that funds be set aside for up to eight more State high blood pressure education programs. These programs have served to expand public and professional knowledge of the dangers of high blood pressure, and the effectiveness of early detection treatment.

Dr. Levy, would you please tell us the eight new States which are receiving funding now?

Dr. LEVY. The committee made that recommendation in their report this past year. We had four States already involved at that time. The States include Connecticut, Maryland, South Carolina and California.

The recommendation for up to eight more State programs was received by the Institute, and we have acted on it. We have released a request for proposal—an RFP—to solicit additional States that did not compete successfully earlier. The due date for these proposals has not yet been reached. We have heard from some 20 States who expect to respond. How many of those States we will be able to support, Senator Schweiker, is not clear. The statewide programs that we are currently supporting cost close to $700,000 to $800,000 per State.

The concept in the statewide hypertension control program was that each State would do a baseline survey to identify the proportion of the population at risk with hypertension, look at what was happening in cardiovascular disease, stroke and heart attack mortality and morbidity, and then implement a coordinated statewide implementation plan to control high blood pressure. Finally, 4 or 5 years later, we would repeat the survey and see what has happened vis-a-vis blood pressure control and stroke and heart attack morbidity and mortality.

The first four States have completed their initial survey phase. They are just now implementing their control plans. The additional States that we will add obviously will be more than 1 year behind these first States, but since we have many more States with no coordinated programs we should be about to see and evaluate the

effects of these aggressive programs to bring high blood pressure control to all our citizens.

PROGRAM PRIORITIES

Senator SCHWEIKER. In view of the decline that you just cited, in terms of heart disease and stroke, et cetera, wouldn't this be a top priority program?

Dr. LEVY. Well, the problem, Senator Schweiker, is that there are so many top priority programs, high priority areas in heart, lung, and blood diseases. The statewide hypertension program is just one effort to bring high blood pressure under control, and this is just one of the many things that we can do to lower cardiovascular disease morbidity and mortality in the United States.

Just in hypertension demonstration and education alone, we have programs that are now focusing on the work setting, focusing on bringing blood pressure control to the minority groups, focusing on rural and urban community health centers, as well as focusing on even more fundamental questions, such as how to achieve adherence to regimens involving blood pressure lowering medication.

We are also working on finding better ways to control hypertension. As I described in my opening statement, the fact is that we can still use more effective blood pressure lowering drugs, and we are developing them. We have to focus some attention on drug development, testing, and validation.

Finally, hypertension is still called "essential" in about 90 percent of all cases. This term "essential" hides the fact that we don't know its cause. A hypertension task force this year, Senator Schweiker, has recently reported their findings at our last National Heart, Lung, and Blood Advisory Council meeting. They made the recommendation for more research in several new opportunity areas to help to define the cause or causes of hypertension. If we can define the cause of hypertension, we might be able to do away with the drugs that we are using now, and might be able to prevent it.

They focused on about eight opportunity areas in basic research, including the effect of salt and weight control on blood pressure, the effect of higher neural control of the heart and vessels by the central nervous system, the effect of veins, the microcirculation, and vessel reactivity itself on hypertension as well as the effect of several body-made hormones.

So that even in the hypertension area, we face what we might call "the problem of being between a rock and a hard place." There are many research opportunities and questions to pursue, due to gaps that still exist in our knowledge development.

There are also concepts that remain yet to be validated. Dr. Fredrickson mentioned in his opening statement the importance of defining what role high blood pressure control has to play in the elderly. Will we produce more problems in the elderly by controlling high blood pressure, or will we diminish dementia, stroke, and heart attack?

And then there are the education and demonstration activities. We have to make very hard decisions, Senator Schweiker, and it is a very difficult time.

TRAINING

Senator SCHWEIKER. Last year, Doctor, you painted a somewhat dismal picture as to the number of Ph. D. and M.D. trainees in the heart disease area.

What does your fiscal 1980 budget recommend for this training program, and what is the situation currently?

Dr. LEVY. The situation is, as I have just indicated, very difficult, and especially so in training. In fiscal 1979, we had no training budget appropriated, and because we are therefore, in fiscal 1979, operating under a continuing resolution, the spending level is identical to what we had in fiscal 1978.

We find ourselves with only $63,000 for all new training starts in fiscal 1979. That means, Senator Schweiker, that we are only funding four new individual fellowships this year, or I should say, we are essentially not funding any new training starts. Our usual new training funding is about $6 million a year.

In fiscal year 1980, we hope to move back toward the number of trainees and the training level that we had in fiscal 1978.

If an additional 5-percent reduction in budget should occur, as was mentioned by the chairman earlier, we would find ourselves, then, essentially funding no new training starts for the next 2 consecutive fiscal years—for the fiscal year we are now in, and for the fiscal year that we are testifying to, fiscal 1980.

So, in training, indeed, we have a very difficult picture. We will not be starting any new training in fiscal year 1979. Unfortunately, there was no authorization for training when this committee met last year, and so there was no formal appropriations for training.

5-PERCENT CUTBACK

Senator SCHWEIKER. All right. On behalf of Chairman Magnuson, he wants to ask this next question of every Institute Director, and I guess we did ask it already, of Dr. Upton. What we will do is ask you to supply the answer for the record. The question is how many areas do you think could be cut back within your Institute?

In other words, what are some lower priority programs that in tight fiscal times can be sacrificed?

I think this goes to the 5-percent cut question. Would you and the other Directors supply for the record where you would cut back on a 5-percent cutback?

Dr. LEVY. We would be happy to supply this for the record. We will respond to Senator Magnuson.

[The following questions were not asked at the hearing, but were submitted to the Department for response subsequent to the hearing:]

5 PERCENT REDUCTION

Question: What would be the impact of a 5 percent reduction?

Answer: In developing the response to this question, we utilized the following general guidelines, noting that the 5 percent reduction would compound the impact already felt from inflation by the NIH programs.

1. Protecting the science base is paramount, and therefore research project grants must sustain the least reduction. Because it is equally important to maintain a flow of new ideas entering the system, funding of new and competing awards would not be cut below the level in the 1980 President's Budget. Non-competing grants would have to be renegotiated downward from commitment levels by 3 to 5 percent.

2. The NIH intramural research program would assume its share of the reduction. This would be achieved primarily by reducing research supplies and equipment, since personnel costs cannot be reduced easily.

3. Administrative Management costs would also be reduced, mainly in supplies and equipment; and program evaluation activities would also be cut.

4. Research training would be reduced, the amount depending upon the long-range expectations for support of biomedical research. The need to increase training stipends at the same level of support would drop the number of trainees in the system by 15 percent in 1980. This activity would be further reduced if it were intended to reduce biomedical research capacity permanently.

5. Several areas other than research project grants would be reduced less than 5 percent:

   - The National Library of Medicine, a unique scientific resource requiring a certain sustained level of support, would be reduced 4 percent.

   - The Office of the Director, consisting mostly of personnel costs which are difficult to reduce without a reduction in force, would be cut 3 percent.

   - Services furnished centrally by the NIH require a certain level of support to maintain the NIH research program. An example of this is the NIH Clinical Center, a unique resource which must sustain a certain level of operation or become inefficient. The central service activities would be reduced 2.5 percent.

   - There would be no reduction in the Buildings and Facilities account, since the modest amount requested is the very minimum necessary to maintain our existing plant and facilities.

6. Generally, the greatest decline in support would be for research training, certain types of research centers, research and development contracts, administrative management, and cancer construction activities.

It is the considered view of the Director, NIH, that any substantial cut in resources for NIH, or any of its components, should be accompanied by changes in current legislative authorities. The most important requirement would be the need to provide the Director, NIH, with limited reprogramming authority between Institute appropriations, under appropriate control, in order to maintain the critical balance of overall effort during severe austerity. There would also have to be changes in some categorical statutory requirements, for example, the requirement that 15 percent of the NHLBI appropriation go into blood and 15 percent into lung activities, and relief from some of the numerous disease-oriented mandates upon Institutes. The impact of sudden, substantial decreases -- or increases -- on an institution like biomedical research can be very harmful. Changes need to be prepared for and accomplished gradually to minimize the loss of irreplaceable people, things and ideas which are at stake in so creative an endeavor.

The following tables summarize by organization and by mechanism how I would distribute an overall 5 percent reduction in the NIH 1980 request:

NATIONAL INSTITUTES OF HEALTH

Impact of Proposed Five Percent Reductions - By Organization

(dollars in thousands)

	1980 Budget Request	Five Percent Reduction	1980 Reduced Level
NCI	$936,958	-$47,047	$889,911
NHLBI	507,344	-25,475	481,869
NIDR	66,118	-3,320	62,798
NIAMDD	305,746	-15,352	290,394
NINCDS	212,322	-10,661	201,661
NIAID	190,202	-9,551	180,651
NIGMS	280,378	-14,079	266,299
NICHD	204,381	-10,262	194,119
NEI	104,528	-5,249	99,279
NIEHS	79,012	-3,967	75,045
NIA	56,510	-2,838	53,672
DRR	154,199	-7,743	146,456
FIC	8,989	-451	8,538
Subtotal	3,106,687	-155,995	2,950,692
NLM	41,431	-1,657	39,774
OD	21,062	-631	20,431
B&F	3,250	--	3,250
Total	3,172,430	-158,283	3,014,147

Note: NLM reduced by 4 percent.
OD reduced by 3 percent.

NATIONAL INSTITUTES OF HEALTH

Impact of Proposed Five Percent Reduction

Summary Mechanism

(dollars in thousands)

	1980 Budget Request	Five Percent Reduction	1980 Reduced Level
Research Grants			
Research Projects	$1,372,375	-$34,799	$1,337,576
Noncompeting	(1,092,855)*	(-34,799)	(1,058,056)
Competing	(279,520)	(--)	(279,520)
Research Centers	338,115	-23,642	314,473
Other Research	190,434	-9,766	180,668
Subtotal	1,900,924	-68,207	1,832,717
Training	151,641	-14,069	137,572
Research & Development Contracts	428,371	-38,366	390,005
Intramural Research	330,488	-14,421	316,067
Direct Operations	176,329	-14,423	161,906
Program Management	34,324	-1,028	33,296
Cancer Control	69,610	-3,481	66,129
Construction	15,000	-2,000	13,000
Subtotal	3,106,687	-155,995	2,950,692
National Library of Medicine	41,431	-1,657	39,774
Office of the Director	21,062	-631	20,431
Buildings & Facilities	3,250	--	3,250
Total	3,172,430	-158,283	3,014,147

* Includes administrative supplements.

The Institutes developed their own plans for absorbing the 5 percent reduction following the above general guidelines. The National Library of Medicine and the Office of the Director also prepared plans based on a 5 percent reduction as requested. These submissions follow.

NATIONAL CANCER INSTITUTE

FIVE PERCENT REDUCTION

Question: What is the impact of a 5% reduction on your program?

Answer: A 5% reduction would result in decreases to all areas of the National Cancer Program, including research, resource development and cancer control.

Research

Cause and Prevention Research:

There would be a delay or elimination in the testing of new chemicals for carcinogenicity through long-term in vivo tests. There would be a reduction in short-term in vitro testing for carcinogenicity. Research involving a better understanding of the mechanism of action of carcinogens, will be delayed.

Epidemiologic studies to uncover the environmental causes of cancer in high risk communities would be reduced.

Studies to determine the effectiveness of a less hazardous cigarette will be reduced.

Reductions in viral oncology will result in the curtailment of studies on the mechanisms by which genetic information interacts with host cells and ways to detect the presence of cancer-causing genes.

In nutrition, planned areas of emphasis that will not be conducted include: development and validation of methodologies to evaluate nutritional approaches to carcinogenesis inhibition; evaluation of various food substances which may inhibit or promote the carcinogenesis process; and the effects of food manufacture/cooking on formation of carcinogens.

Detection and Diagnosis Research:

Sharply reduce the Cytology Automation Program. This would delay the development of an efficient instrument for automated cytodiagnosis which might bring early diagnosis of cancer of the cervix to a large group of women.

Reduce the Immunodiagnosis Program which would delay development of cancer diagnosis blood tests which could be used on large numbers of people without the hazards of x-rays or other potentially harmful methods.

Treatment Research:

New projects for evaluating dietary practices and studies on terminal care of cancer patients will not be initiated. Ongoing projects on psychosocial problems, development of rehabilitation technologies and pain management will be terminated.

There will be decreases in Clinical Trials research in the following areas: Phase III and Phase IV studies (comparative and combined modality studies) will be decreased in number; Phase I and II testing of investigational drugs, immunotherapeutic trials of immune modalities, Phase II testing of new agents in gastrointestional cancer will be reduced in number; centralized monitoring of clinical trials will be terminated; clinical studies planned in the areas of endometrial cancer will not be initiated; new toxicity models will not be undertaken.

Fewer studies on the development and evaluation of new markers will be done.

Decreased funding would be available for non-competing traditional investigator-initiated research grants and program project grants in the areas of biochemistry, pharmacology and clinical oncology.

Cancer Biology:

Research in fundamental immunology directed toward an understanding of how cells of the immune system recognize and destroy tumor cells will be reduced. This will delay development of the information base which may be essential for the development of rational immunotherapy of cancer.

Research in tumor biology directed towards an understanding of how cancer cells spread through the body (metastasize) from the primary tumor will be decreased. This will delay the development of an understanding of metastasis that might provide the basis for rational treatment of early tumors.

Resource Development

Cancer Centers Support:

Cancer Centers Support would be decreased by $3.165 million resulting in 5 less awards in 1980. The Cancer Centers serve as national resources for research, education, training and community outreach. With a decrease in awards, this role would be significantly compromised.

Research Manpower Development:

The National Research Service Awards (NRSA) will be reduced by $2.145 million. A necessary increase in stipends combined with a 5% reduction will result in a reduction of 495 Full Time Equivalants. While this will impact on the research area of cause and prevention, detection and diagnosis, and treatment, it is especially important in the areas of cause and prevention where the need for toxicologists and pathologists is increasing and the resources for training are decreasing.

The Clinical Education Program would be reduced by $.545 million resulting in a decrease of 4 awards.

The Research Career Program will be reduced by $.214 million and 6 awards, reducing the number of potentially effective and productive scientists available to conduct research.

Construction

The construction and renovation program will be reduced by $2 million. A recent survey has identified the need to upgrade animal research facilities in that almost 40% of the cancer research animals are housed in facilities which do not meet DHEW standards for animal care and biohazard containment. The reduction would impair our capability to meet these requirements.

Cancer Control:

New programs which would have to be delayed, cut back, or eliminated include the community clinical oncology demonstration programs, maxillofacial prosthodontist training, and activities related to mammography clinical trials.

Mechanims Summary (000 $)

	1980 Estimate	% Reduction	1980 Reduced Level
Research Grants			
Research Projects	$282,774	-3,978	$278,796
Research Centers	63,294	-3,165	60,129
Other Research	68,990	-3,102	65,888
Subtotal	415,058	-10,245	404,813
Training	20,410	-2,145	18,265
Research and Development Contracts	225,793	-18,592	207,201
Intramural Research	103,606	-4,985	98,621
Direct Operations	75,180	-5,031	70,149
Program Management	12,301	-369	11,932
Cancer Control	69,610	-3,481	66,129
Construction	15,000	-2,000	13,000
Total NCI	$936,958	-46,848	$890,110

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

To achieve a 5% reduction in the NHLBI budget (a reduction of $25 million, we would propose to (see the table at the end of this presentation):

(1) eliminate limited program expansions for which funds are included at the President's budget level:

o Specialized Centers of Research in Ischemic Heart Disease (heart attack). The original 9 centers complete their five-year period of commitment in 1979. They have already been competitively reviewed for funding in 1980. The Advisory Council has recommended the renewal of the active 9 centers, plus 2 additional centers, a total of 11 centers. The Ischemic Heart Disease Specialized Centers of Research have been a successful mechanism for providing research advances in the early detection, diagnosis, and treatment of heart attack.

o additional new training starts. This program is being reduced in 1979 since there are no dollars available for new training starts under the continuing resolution. In 1980 we had planned to restore this program to pre-1979 levels (essential to the future health of the biomedical research community) (see item number 3 under further reductions below).

After curtailing these programs we would achieve further reductions by:

(1) reduction in funds committed, through renegotiation, for all non-competing research grants by an average of 4.7%, from $185,629,000 to $176,930,000 (a savings of $8,699,000).

(2) Reduction of approximately 5%, through renegotiation, in all center awards (a savings of $3,150,000). Included in this reduction would be:

o each of the 46 Specialized Centers of Research targeted at basic and clinical research in specific heart, lung, and blood diseases;

o the 3 Research and Demonstration Centers;

o the 10 Comprehensive Sickle Cell Centers;

(3) reduce by 12.5% our training programs (a savings of $3.1 million).

This reduction, in addition to the need to increase training stipends in 1980, will result in:

o loss of 487 full-time training equivalents (FTE's), a percentage loss in FTE's of 30% compared to the President's budget;

(4) reduce research and development contracts by 5% (a savings of approximately $4 million). Clinical trials constitute approximately $60 million of the $92.8 million total contract dollars. They cannot be reduced. The remaining contract budget would thus be reduced by approximately 15%.

o this would reduce our worksetting, community, and state-wide hypertension control program.

o it would curtail new nutrition education programs as well as other education activities in lung disease and sickle cell disease.

o it would also reduce noninvasive diagnostic device development activity.

(5) reducing Intramural Research by $1,572,000.

o This could idle manpower, space, and utilization of equipment on hand, including hospital research beds and involve the possibly closing of one or more research laboratories.

(6) reducing Direct Operations and Program Management by $2,629,000.

o This would curtail technical assistance given to contractors and grantees during pre-award negotiations, program monitoring, and post-award evaluations. It would diminish travel, information dissemination, direct education activities, and clinical trial monitoring. It would make oversight of grant and contract operations very difficult when coupled with the need to renegotiate existing awards.

Achievement of 5% Reduction
By Mechanism
(dollars in thousands)

Research Grants	
Research Project Grants	$8,699
Research Centers	4,150
Training	3,100
R & D Centers	4,850
Intramural Research	1,572
Direct Operations	2,449
Program Management	180
Total	$25,000

NATIONAL INSTITUTE OF DENTAL RESEARCH

Question: What is the impact of a 5% reduction on your program?

Answer: A reduction of 5% would impact on NIDR program efforts in the following ways:

- Decrease capacity to adequately fund demonstration of community-based fluoride mouthrinse programs for upper-grade school children.
- Preclude/delay the funding of one new Clinical Research Center.
- Curtail the initiation of controlled clinical trials of dental implants.
- Decrease capacity to fund contract on cleft lip/palate record system necessary to accumulate epidemiological data-base in the U.S.
- Reduce resources for funding of basic studies on pain control mechanisms.
- Curtail research on vitamin deficiency, protein deficiency and excess and mineral metabolism; role of viruses in etiology and pathogenesis of ulcerative diseases in the oral cavity, and early detection of oral malignancies.
- Cut in basic science research, - further reducing the likelihood that the 5 Dental Research Centers can move into clinical application areas.
- Curtail all large scientific equipment purchases.
- Freeze positions in the scientific and administrative management of NIDR grant, contract and computer activities as they become vacant.
- Freeze positions on the Institute's Director's immediate staff, including Program Planning and Evaluation, Office of Scientific and Health Reports, as well as Personnel, Financial and Administrative Support Services as they become vacant.

SUMMARY MECHANISM TABLE
(in thousands)

	FY 80 Estimate Amount	5% Reduction Amount	FY 1980 Reduced Level Amount
Research Grants			
Research Projects	25,831	- 401	25,430
Research Centers	9,178	- 459	8,719
Other Research	1,408	- 70	1,338
Training	4,198	- 500	3,698
R & D Contracts	5,048	-1,241	3,807
Intramural	13,071	- 413	12,658
Direct Operations	6,153	- 185	5,968
Program Mgmt.	1,231	- 37	1,194
Total	66,118	-3,306	62,812

NATIONAL INSTITUTE OF ARTHRITIS, METABOLISM, AND DIGESTIVE DISEASES

Question: What would be the impact of a 5% reduction on your program?

Answer: Because over 80% of our program is in research grants and contracts, the majority of the money would come from these areas, however, reductions in intramural research and direct operations cut much deeper than is readily apparent because they must be made from the smaller amounts which are "controllable" rather than such items as salaries and benefits. Because of an increase in trainee stipends, no additional cut could be made. Briefly, such a reduction would require:

- 80% of the reduction to be made in basic research.
- a 6% forced negotiation of all non-competing research projects.
- reduction in the number of research trainees and fellowships by 22% and make no new awards.
- curtailment of nearly all new equipment purchases in intramural research.
- elimination of all Institute support program evaluation projects and the reduction of program planning efforts.
- discontinuation of 3 Kidney Special Centers of Research; 2 Diabetes Research and Training Centers; 3 Multipurpose Arthritis Centers; and make no new centers awards.
- cancellation of a planned clinical trial in diabetes.
- reduction of research on the treatment of end-stage renal disease by 10%.

Summary Mechanism Table

	1980 Estimate	5% Reduction	Reduced Level
Research Grants			
Research projects	$180,721,000	$7,616,000	$173,105,000
Research centers	26,625,000	3,350,000	23,275,000
Other research	11,265,000	---	11,265,000
Training	17,877,000	---	17,877,000
Contracts	16,459,000	2,000,000	14,459,000
Intramural Research	39,188,000	1,080,000	38,108,000
Direct Operations	12,355,000	1,194,000	11,161,000
Program Management	1,256,000	50,000	1,206,000
Total	305,746,000	15,290,000	290,456,000

Impact of Proposed Reduction of the 1980 President's Budget

The proposed reduction for 1980 of 5% would be a decrease of $10,616,000 from the President's Budget of $212,322,000. Basic research would be reduced by $2,700,000. Investigator-initiated research grant projects would be maintained at the 1979 funding level. Funds for National Research Service Awards would permit funding of all commitments including the increased stipend levels. No new awards would be made and one-third of the planned renewal awards could not be made, with a consequent erosion of the neurological and communicative research manpower pool.

Communicative Disorders Program Reduction of $1,290,000: Two competing renewal Research Centers could not be funded in the areas of hearing and speech disorders. Research contracts on speech and language disorders in children would be curtailed.

Neurological Disorders Program Reduction of $2,841,000: Three competing renewal Research Centers would not be funded in the areas of epilepsy, neuromuscular disorders, and multiple sclerosis. Contracts for the Comprehensive Epilepsy Centers and information dissemination activities would be reduced by 20% and development of new drugs for neurological disorders would be delayed.

Stroke and Nervous System Trauma Program Reduction of $2,013,000: Three ongoing renewal Research Centers on stroke and on head injury and spinal cord injury would be phased out. Implementation of the planned Comprehensive Trauma Centers would be postponed.

Fundamental Neurosciences Program Reduction of $430,000: Contracts for the Brain Information Center and the Neurosciences Research Program would be seriously reduced.

Intramural Research Program Reduction of $3,259,000: This reduction would seriously impair the potential for enhanced insights into such brain disorders as stroke, head injury, epilepsy, and various mental diseases by deferring the purchase of a cyclotron required for the production of the isotopes utilized in the intramural research Positron Emission Transverse Tomography Program. This program would be continued at a minimal level.

Direct Operations and Program Management Reduction of $783,000: Program evaluation activities would have to be drastically reduced by two-thirds of the planned activity.

	1980 Estimate	5% Reduction	1980 Reduced Level
Research grants			
Research Projects	$102,089	$ --	$102,089
Research Centers	28,300	-3,995	24,305
Other Research	8,240	--	8,240
Training	7,322	-329	6,993
R&D Contracts	19,319	-2,700	16,619
Intramural Research	32,964	-2,809	30,155
Direct Operations	12,226	-773	11,453
Program Management	1,862	-10	1,852
Total	$212,322	-$10,616	$201,706

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Question: What would be the impact of a 5% reduction on your programs?

Answer: A 5% reduction is $9.5 million and would impact primarily on our more applied and developmental research implemented by contract, on intramural research, and on training. It would require us to negotiate continuing grants downward by an average of 2.5 to 3.0%. Specifically, it will:

- Reduce contracts related to vaccine development by terminating those related to some aspects of influenza and other respiratory viruses and by preventing new awards for testing of varicella and other vaccines. Also reduce related intramural research on virus diseases.

- Reduce contracts related to antiviral drugs and the procurement of interferon for clinical trials. Also reduce intramural research.

- Terminate contracts for evaluation of histocompatibility matching in survival of kidney organ transplants. Prevent planned increase of serum bank to meet increased demands for histocompatibility typing sera.

- Reduce the planned increase in tropical diseases research projects. Prevent the award of two Centers in FY 1979 to avoid continuation costs in 1980 and an additional center in 1980.

- Prevent competing awards for Researh Career Development, eliminate predoctoral training and reduce number of new postdoctoral trainees by one-third, creating a future shortage of new talent needed to replace scientists leaving research.

- Cause a major reduction in support to research workshops, conferences and site visits.

- Prevent needed renovation to intramural animal spaces and delay procurement of needed replacement equipment.

Mechanism Distribution of 5% Reduction
(Dollars in thousands)

	1980 Request	5% Reduction	Reduced Level
Research Grants			
Research Projects.	$110,477	$-2,471	$108,006
Research Centers .	4,462	-1,332	3,130
Other Research . .	5,024	-525	4,499
Training	7,847	-500	7,347
R & D Contracts. . .	17,335	-2,335	15,000
Intramural Research.	34,090	-1,247	32,843
Direct Operations. .	9,005	-1,000	8,005
Program Management .	1,962	-100	1,862
Total. . . .	190,202	-9,510	180,692

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NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES

Question: What would be the impact of a 5% reduction on your program?

Dr. Kirschstein: A five percent reduction would mean a cut of roughly $14 million below the President's Budget, or $11 million below the Institute's FY 1979 funding level. The impact of such a reduction would be as follows:

- A $2.5 million reduction in non-competing investigator-initiated grant awards. Programs affected most would be Pharmacology-Toxicology (P-T), especially in bio-related chemistry, and Physiology and Biomedical Engineering (PBME), primarily in such areas as biomathematics, biostatistics, diagnostic radiology, and anesthesiology research.

- A $7.1 million, or thirty percent cut in projected dollar support for competing research training awards, with heaviest impact falling on predoctoral awards. Such a short-term reduction in training would be less likely to do substantive harm than a further reduction in research support. This would be applied to all NIGMS programs, except the Minority Access to Research Careers(MARC) Program.

- A $2.7 million cut in research centers support across all programs. Two centers would be eliminated entirely, one in Molecular Pathology and one in Trauma and Burn research. All others would be reduced in amount.

- A $1.7 million reduction in other areas with a substantial cut being applied to Direct Operations on assumption Institute contributions to the NIH Management Fund and DHEW Evaluation Fund, can be reduced. Five intramural research fellows would be eliminated and Research Career Development Awards reduced $342,000, impacting most on the P-T and PBME programs.

Budget Mechanism
(dollars in thousands)

	F.Y. 1980 President's Budget Amount	5% Reduction Amount	F.Y. 1980 Reduced Level Amount
Research Grants:			
Research projects..	$200,073	-$2,461	$197,612
Research centers...	19,759	-2,700	17,059
Other research.....	4,470	-342	4,128
Total, research..	224,302	-5,503	218,799
Training Programs....	45,422	-7,118	38,304
R & D Contracts.....	800	-200	600
Intramural Research..	586	-140	446
Direct Operations....	7,650	-1,008	6,642
Program Management...	1,618	-49	1,569
Total, NIGMS.....	280,378	-14,018	266,360

NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

Question: What is the impact of a 5% reduction on your program?

Answer:

($ in 000)

Mechanism	1980 Estimate	5% Reduction	1980 Reduced Level
Research Grants			
Research Projects	$107,299	-$2,821	$104,478
Research Centers	24,496	-2,450	22,046
Other Research	2,837	---	2,837
Research Training	9,820	---	9,820
Research and Development Contracts	27,784	-3,141	24,643
Intramural Research	20,940	-800	20,140
Direct Operations	9,262	-949	8,313
Program Management	1,943	-58	1,885
Total	204,381	-10,219	194,162

A 5% reduction in the NICHD budget will have the following consequences:

- a reduction of some 3% in research project grants would reduce the research effort over a broad range of reproductive biology and developmental biology studies, in the Population program and in the Research for Mothers and Children program, respectively. These reductions would curtail on-going projects including initiatives in high risk pregnancy, adolescent health and in the prevention of unwanted pregnancy.

- a 10% reduction in research center grants would curtail the establishment of Clinical Nutrition Research Units, part of a major NIH initiative in nutrition.

- An 11% reduction in research and development contracts would seriously affect the implementation of new initiatives in nutrition, smoking and adolescent pregnancy.

- A reduction of $.8 million in the Intramural Research Program would impact most seriously on work related to reproduction, early development and the effect of drugs on fetal development. Purchase of needed equipment and renovation of space would be eliminated in the area of pregnancy research.

- A $1 million reduction in Direct Operations and Program Management would cause elimination of a variety of critical grant and contract management efforts and in areas of program evaluation and dissemination of research results.

NATIONAL EYE INSTITUTE

Question: What is the impact of a 5% reduction on your program?

Answer: The 5% reduction in FY 1980 will serve as a harsh reminder to the research community of the fiscal instability that periodically disrupts the biomedical research enterprise. Specific projects which will not be funded or considerably impeded appear under their respective programs below:

Retinal and Choroidal Diseases:

- ocular melanoma
- neural retina (neurotransmitter) studies

Corneal Diseases:

- corneal drug penetration
- metabolism and nutrition (role of trace elements, vitamins and minerals--and levels--in ocular disorders)

Cataract:

- expanded studies of protein chemistry of lens
- slowing of aldose reductase (and inhibitors) research

Glaucoma:

- clinical trials on application of laser technology to surgical treatment of glaucoma

Sensory-Motor Disorders and Rehabilitation:

- clinical application of psychophysic and physiologic optic techniques
- slowing of studies on eye movement disorders

	1980 Estimate	5% Reduction	1980 Reduced Level
Budget Mechanism ($000):			
Research Grants:			
Research Projects	$ 70,634	-$3,980	$66,654
Research Centers	5,790	- 302	5,488
Other Research	3,890	- 197	3,693
Training	4,643	--	4,643
R & D Contracts	6,000	--	6,000
Intramural Research	9,495	- 313	9,182
Direct Operations	2,908	- 380	2,528
Program Management	1,168	- 54	1,114
Total, NEI	$104,528	-$5,226	$99,302

NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES

Prediction, detection and assessment of environmental diseases and disorders: decrease of $1,527,000. In order to absorb this decrease, ongoing investigator-initiated research projects begun in FY 1977, 1978, and 1979, dealing with the incidence and prevalence of environmentally-induced diseases and disorders; development of test methodology, including short-term assays; and risk extrapolation methodology would be reduced from the levels originally approved by Study Section and Council. These reductions would result in the lay-off of staff, the deferment of research expenses, and the subsequent slow-down in efforts and production of research results. Targeted research conducted by contract related to the development of specific test methodologies and the conduct of tests as part of the National Toxicology Program plan would be slowed down.

Mechanisms of environmental disease and disorders: decrease of $972,000. Funding of investigator-initiated research projects elucidating the biochemical mechanisms of toxicity and mechanisms of induction of environmental diseases approved and initiated in 1977, 1978 and 1979 would be reduced. Targeted research activities in the fields of pharmacokinetics and the assessment of toxicity of specific environmental agents would be reduced or curtailed.

Environmental health research and manpower development resources reduction of $559,000. Plans to add an additional Marine Biomedical Research Center would be deferred from FY 1980 and FY 1981. Increased research training efforts would be deferred. A reduction of approximately 149 full-time equivalent training positions would be sustained.

Intramural research, direct operations and program management: decrease of $892,000. This decrease will require the curtailment of necessary travel; the procurement of supplies and services needed to support ongoing research programs. Important in-house research efforts including epidemiologic studies, studies of the mechanisms of genetic mutation, and studies of the metabolism and action of toxic compounds will be seriously disrupted, and the time from initiation to completion of basic research projects will be markedly protracted.

Summary Mechanism Table
(dollars in thousands)

	1980 Estimate	5% Reduction	Reduced Level
Research grants.....	$24,822	-$1,424	$23,398
Research centers.....	10,197	-334	9,863
Other research.....	864	-215	649
Training.....	6,568	-225	6,343
R & D contracts.....	8,292	-860	7,432
Intramural.....	23,490	-523	22,967
Direct operations.....	2,580	-304	2,276
Program management....	2,199	-65	2,134
Total.....	79,012	-3,950	75,062

NATIONAL INSTITUTE ON AGING

Question: What is the Impact of a 5 percent reduction on your program?

Answer: NIA reductions would be based on such criteria as susceptibility of a program element to short-term, temporary reductions; minimal impact on current commitments and new, high-quality individual investigator research; and minimal impact on recently developed momentum. A 5 percent reduction would have the following effect:

- Scheduled further additions of women to the Baltimore Longitudinal Study would not occur;
- Fewer Longitudinal Study subjects would inhibit intramural immunology, neurosciences, stress and coping, and nutrition studies;
- The Bethesda intramural program in the neurosciences would not be implemented;
- Development of epidemiology data bases (senile dementia and ethnic population studies) would be curtailed;
- An incipient prosthetics program would be reduced or eliminated;
- May impact on clinical nutrition units and would eliminate currently supported core center grant
- Would reduce the number of FTEs in training from 143 to 118;
- Noncompeting research grants would be reduced by 4 percent.

Summary Mechanism Table
(dollars in thousands)

	1980 Estimate	5% Decrease	1980 Reduced Level
Research Grants			
Research projects	31,797	-948	30,849
Research centers	318	-318	---
Other research	2,600	-100	2,500
Training	1,984	-70	1,914
R&D contracts	4,500	-670	3,830
Intramural	11,058	-539	10,519
Direct operations	2,885	-173	2,712
Program management	1,368	-8	1,360
Totals	56,510	-2,826	53,684

DIVISION OF RESEARCH RESOURCES

Question: What is the impact of a 5% reduction on your program?

Answer: A reduced capability to sustain research resources that serve as institutional centers of scientific focus and collaboration for a wide variety of individual research project grant investigators. Thus, the provision and strengthening of such undergirding cost-effective research resources would be slowed at the very time that greater efficiency in the national biomedical research system is being sought.

- The competitive Biomedical Research Development Grant Program for new, small and developing institutions striving to strengthen and expand their biomedical research activities would be terminated. Newly emerging health professional schools would be restrained from achieving their health research and education potential with some subsequent impairment of competence in their development of health care practitioners (-$3,300,000).
- A major national Biotechnology Resource utilized as a source of biostatistical and biomathematical research computer procedure programs would be terminated. These statistical programs are used extensively in the analysis of very complex data used to validate the scientific conclusions drawn from biomedical research (-$450,000).
- Termination of seven Laboratory Animal Sciences resources; all activities related to institutional animal resource improvement projects and reductions of approximately 9% for 20 ongoing projects. These limitations would terminate productive projects aimed at developing animal models for biomedical research and eliminate several national resources providing blood typing and viral diagnostic services for colonies of nonhuman primates. Current training activities would be reduced 17%, resulting in fewer graduates to fill vitally needed roles in central animal resource programs (-$1,547,000).
- The Clinical Associate Physicians program would be terminated. This program has been most successful in retaining young physicians in academic career positions in clinical investigation. Distribution of the newly created data management system (CLINFO), specifically designed to manage clinical research projects, would be halted. Two resource contracts designed to foster the use of the especially powerful techniques of gas chromatography/mass spectroscopy in clinical research applied to drug action and protein metabolism would be terminated (-$1,302,000).
- The extension of the Minority Biomedical Support Program to two-year colleges which would foster the inclusion of native American Indian students would be delayed. Thus, 70 two-year colleges and 25 reservation-based American Indian post-secondary institutions would not be able to compete for this specialized funding (-$450,000).
- The capability of the Division's Direct Operations and Program Management to monitor and evaluate the progress and impact of Research Resource Centers and Programs would be further constrained (-$661,000).

	1980 Estimate	5% Reduction	1980 Reduced Level
Research Grants:			
Research Centers	$ 78,465,000	-$1,002,000	$ 77,463,000
Other Research	65,687,000	- 5,215,000	60,472,000
Training	550,000	- 82,000	468,000
Res. & Dev. Contracts	4,245,000	- 750,000	3,495,000
Direct Operations	4,142,000	- 628,000	3,514,000
Program Management	1,110,000	- 33,000	1,077,000
Total:	$154,199,000	-$7,710,000	$146,489,000

FOGARTY INTERNATIONAL CENTER

Question: What is the impact of a 5% reduction on your program?

Answer: Should the Fogarty International Center be required to take a 5% reduction, we would plan the following:

- In order to serve the fellowship programs, the conference programs must be reduced disproportionately.
- We must be able to absorb management cuts by reducting travel, supplies, and equipment.
- Our International Research Fellowships Program will be kept at approximately 100; otherwise, it becomes hardly viable. This is because we invite the nominating committees of the participating countries, which number something over 40, to send in 6 nominees.
- The Senior International Fellowship Program is a new one operating only since 1975. We cannot consider cutting it more. That is why we are trying to preserve it by taking more money from the Conference Program.
- The Gorgas Memorial Institute will receive a proportionate cut.

Fogarty International Center

	1980 President's Budget	5% Reduction	Reduced Level
Grants			
Gorgas Memorial	$1,700,000	$85,000	$1,615,000
Program Management	306,000	15,000	291,000
Direct Operations	6,983,000	349,000	6,634,000
Total	8,989,000	449,000	8,540,000

NATIONAL LIBRARY OF MEDICINE

Question: What is the impact of a 5 percent reduction on your program?

Answer: Faced with the necessity of a 5 percent reduction, NLM would advocate the deferral of its new computer procurement and replacing it with some enhancement of its present equipment. This decision would not adversely effect services and would result in a reduction of approximately $1,800,000 in FY 1980 obligations. A $300,000 reduction in Program Management would result in the curtailment of review and evaluation activities, staff training, and reduction of funding for support services furnished centrally by NIH.

(in thousands)

Activity	1980 Pres. Budget	5% Reduction	1980 Reduced Level
Med'l Lib. Asst.....	8,625	---	8,625
Lister Hill Nat'l Ctr. for Biomedical Communications.....	5,328	---	5,328
Nat'l Medical A/V Center.....	3,768	---	3,768
Library Operations.....	14,283	-1,800	12,483
Toxicology Information..	2,240	---	2,240
Program Management.....	7,187	-300	6,887
Total.....	41,431	-2,100	39,331

OFFICE OF THE DIRECTOR

Question: What would be the impact of a 5% reduction in your program?

Answer: A reduction of five percent in the 1980 appropriation request for the Office of the Director would amount to $1,053,000. We would take this reduction through the following actions:

1. Support in the amount of $635,000 for the NIH share of the redesign and implementation of a department-wide grants and financial system would not be financed.

2. We would impose a freeze on the filling of vacancies as they occur representating approximately sixteen man years of effort for a savings of $273,000. This freeze would result in an overall reduction in central executive direction and management of the NIH.

3. A reduction of $55,000 would be taken in the support items - printing and supplies.

4. The OD contribution to the NIH management fund which provides centrally furnished services to all of the NIH would be reduced by $90,000.

	1980 Request	5% Reduction	Reduced Level
Direct Operations	9,950,000	265,000	9,685,000
Program Management	11,112,000	788,000	10,324,000
Total	21,062,000	1,053,000	20,009,000

SPECIALIZED CENTERS

Question: Last year, you said that pediatric specialized centers of research for heart disease in children are being planned. Can you give us a progress report on this initiative?

Answer: Specialized Centers of Research in Childhood Heart Disease are well into the planning stage. A task force of leading physicians and scientists in the field has recommended that such centers be developed to include investigations which will focus on: development of the much needed basic biomedical knowledge for improvement of the management of congenital heart disease and its ultimate prevention; advancement of knowledge in the development of the conduction system in the heart and the causes and treatment of rhythm and conduction disturbances in newborns, infants and children; and enlargement of the studies of the precursors of adult heart disease (arteriosclerosis and hypertension) in children.

Question: What amount of funding would you anticipate for this program in fiscal '80 and beyond?

Answer: At the present budget level, these centers do not appear in our fiscal year 80 budget plans. We would hope to hold an open competition for these childhood heart disease centers in fiscal year 1981. We would hope at that time to establish 3 to 5 centers at a total cost of approximately 3 million dollars per year for 5 years.

BLOOD BANKS

Question: About three years ago, there was a great deal of publicity and an awful lot of talk about a National Blood Policy. What are we doing in this area, Dr. Levy, and what should we be doing?

Answer: The National Blood Policy was promulgated by DHEW in response to concerns about the adequacy of blood services then available in the USA. It identifies four principal goals: an adequate supply for all the needs of the population, highest standards of quality, accessibility to blood and blood products for everyone, regardless of ability to pay, and efficiency in collection, processing, storage, and utilization. Implementation was entrusted to the American Blood Commission (ABC), representing the private sector, working in partnership with appropriate agencies of the Federal Government. ABC membership includes the three major suppliers of blood (the Red Cross, the American Association of Blood Banks, and the Council of Community Blood Banks), as well as professional and consumer groups (e.g., the AMA, the AHA, the ASCP, the Kidney Foundation, the Leukemia Society, the Hemophilia Foundation, and the Association of Retired Persons, etc.), labor unions, and the general public.

Considerable improvement has occurred with respect to several areas of concern, but in others, progress has been admittedly slow. The risk of post-transfusion hepatitis has been significantly reduced. The once predominant form (Hepatitis B) has been virtually elimi-

nated as the result of research and the introduction of highly sensitive screening tests, made mandatory by the Bureau of Biologics (BoB), FDA. All blood banks are now under the jurisdiction of the BoB. Mandatory labelling of "paid blood" and social pressures have resulted in a marked reduction in the use of commercial donors with additional lowering of the hepatitis risk. The ABC formed several task forces, one of which ("Commonality") has completed its work of standardizing a machine-readable label for automated processing of blood bags, which will greatly reduce the chances of human error. The work of the task force on a National Data Center led to the establishment of such a Center, currently supported by NHLBI, which is in the process of gathering basic information never before available to planners and blood bankers. The ABC Task Force on Regionalization has made some progress in surveying the country and in establishing criteria for the recognition of regional associations intended to lead to resource sharing and adequate services for the population in all regions. The ABC Task Forces on Donor Recruitment and on Utilization have fared less well. However, NHLBI is addressing the issue of utilization through an RFP designed to produce information about current transfusion practices. NHLBI, with the ABC as cosponsor, has initiated annual workshops on Logistics and Management in Blood Banking which bring together scientsits, administrators, industry, and technical experts. These individuals discuss improvements in management and cost control, the relationships between hospitals and blood banks and between blood bankers, surgeons, and anesthesiologists, the chief "consumers" of blood.

NHLBI has from the beginning supported, the task forces of the ABC within the framework of its modus operandi and after peer review of the proposals supported, the task forces of the ABC. It continues to suport two--Data Center and Regionalization--at the present time. The ABC is, however, in need of "core" support, which NHLBI is not in a position to offer. We are aware of attempts to obtain funds for the ABC base operations from private sources to supplement their membership fees. The proposed assessment of a minimal charge--something on the order of 1-5 cents per unit of blood--has met with strenuous opposition on the part of several constituent groups of the ABC. This brings up a point of potential concern regarding the viability of the ABC, namely, the conflicts among the many interest groups represented in the membership. In part, these conflicts reflect differences in philosophy with respect to the responsibilities of the individual family and the community as a whole for assuring the donation of blood. Notably, this difference exists between the American National Red Cross and the American Association of Blood Banks. The National Blood Policy, however, states explicitly that the National Blood Resource should remain pluralistic.

We believe that the situation has materially improved in the years since the promulgation of the National Blood Policy, in part because of the direct and indirect effects of that policy, but no doubt largely because of a number of regulatory actions as well as research and technical advances. Soon it may be well to review the National Blood Policy in the light of these developments, so that it can be updated and refined if necessary.

SICKLE CELL ANEMIA

Question: We understand that there is now a new method for the diagnosis of sickle cell anemia by amniocentesis.

Answer: Yes, whereas previously the method used for prenatal diagnosis required fetal blood, a new method has been developed using amniocentesis, that is, taking a sample of the fluid which surrounds the fetus. Fetal sampling carries a 5-10% risk to the fetus while amniocentesis is known to be a relatively safe procedure.

Question: Can you elaborate upon this a little bit and what the accuracy of the test is?

Answer: Yes, with the DNA of the cells obtained from about 15 ml. of amniotic fluid, and using ultrasensitive radiochromatographic procedures it is possible to identify a unique genetic linkage in most subjects with the sickle cell gene. This method has been used successfully by Dr. Kan in California and to date he has confirmed three diagnoses of sickle cell trait in utero. We cannot yet predict the accuracy with this small number, but it appears to be a very sensitive method. It is estimated that this method could be used to diagnose sickle cell disease in utero in approximately 75% of pregnancies at risk. Unfortunately, the other 20% will require fetal sampling for prenatal diagnosis.

Question: Has there been any interplay between your Institute and the Child Health Institute in developing this program?

Answer: Yes, primarily in the exchange of ideas and sharing of information. Specifically, the NHLBI sickle cell disease program co-sponsored a National Workshop on Prenatal Diagnosis last year with the Charles Drew Medical School in Los Angeles. The Director, NICHD, was actively represented at this meeting. Additionally, data obtained by the Amniocentesis Study supported by NICHD has been used in our program. There is also considerable interaction among the investigators working in this area who are supported by each Institute.

SUCCESSES

Question: Give us some specific examples, if you can, of some successful research advances which are now being used that have been developed strictly with funding from your Institute.

Answer: Just as the improved health care of today is based on the cumulative biomedical research achievements of past years, so are research accomplishments. Contrary to popular conception, such progress in the biological sciences seldom occurs through major independent discoveries or spectacular breakthroughs. Rather, research goals are almost invariably attained by steady, painstaking and usually slow accumulation of knowledge--bit by bit--until some fragment of information fills a crucial gap in the biomedical jigsaw puzzle and thus shows the way to a major advance, and sometimes to a long succession of major advances.

During the past 30 years, great progress has been supported by the National Heart, Lung, and Blood Institute in the prevention, detection, diagnosis and treatment of diseases of the heart, lung, blood, and blood vessels, and in our ability to use blood as a lifesaving medical resource.

In general terms, the Institute supported the studies that identified the risk factors for heart disease. Important new studies are now being conducted on patients who have suffered serious heart attacks to determine the best method to prevent recurrence. Institute programs have contributed to improvement in medical diagnosis of heart attacks. These include studies of new methods to examine changes in the blood and use of the electrocardiogram and radioisotopes to measure the amount of damage to heart muscle.

A significant advance in recent years supported by NHLBI has been the improvement in techniques for noninvasively visualizing the heart in action. There are now a number of ways in which heart function, and therefore dysfunction, can be monitored without causing any discomfort to the patient, methods such as echocardiography and nuclear imaging, both of which produce a visual image of the heart.

Research on the pharmacology of new drugs for hypertension and on their safe, clinical use for treatment has been emphasized. New ways to control the rhythm of the heart and to regulate blood pressure during a heart attack have all become part of the treatment now widely available in modern coronary care units. The Institute's Specialized Centers of Research program in hypertension, arteriosclerosis, and other areas has helped to consolidate many of these research advances.

Public health education programs have also contributed to the decline in deaths from heart disease. The Institute's National High Blood Pressure Education Program has made people more aware of the dangers of untreated high blood pressure as well as of the other promoting traits, signs and symptoms of heart disease so that help is sought more promptly.

The Institute has supported efforts to gain wider acceptance of preventive measures against heart attacks, including smoking cessation, detection and treatment of high blood pressure (hypertension), eating proper foods, and regular exercise.

These are just a few general examples of the progress and advances which have emanated from Institute funding. Specific examples follow. While NHLBI funding had a major role in bringing these products into being, we cannot claim that all of the research leading to these developments was solely funded by the Institute.

Heart and Vascular Diseases

o Heart catheterization for evaluation of heart function and diagnosis of abnormalities within the heart and arterial system originated from early research experiments, extensive use and improvements through research. Catheterization is now a safe, common and highly useful medical procedure evolving from research support.

o Angiocardiography, which is an x-ray film taken after injection of a dye into the blood which is visible by x-ray, was extensively developed in heart research to outline heart chambers and arteries. It is now a well standardized and accepted diagnostic procedure. All medical centers now can perform this diagnostic test safely.

o Cineangiography is a further advance in diagnostic techniques evolving from research use. Motion pictures of the heart or coronary arteries during injection of x-ray visible dye produce a direct view of heart function and of adequacy of blood flow through the coronary arteries. Many individual films are available for detailed evaluation of cardiac or coronary artery function.

o Open heart surgery, which makes possible the correction of a variety of congenital and acquired heart malformations, is now a safe and widely established surgical procedure due to research advances from many special fields. Research findings which have made possible better diagnosis, better preoperative care, better operative procedures and maintenance of the patient during operations and better post operative care make this highly technical management of serious heart problems now almost standard surgical practice in major medical centers.

o Blood vessel surgery to repair, replace, to reestablish adequate blood flow through arteries supplying the heart, brain, kidneys or extremities has reached a high level of technical improvement through knowledge from many similar fields of research. Diagnostic procedures like angiography and blood flow measurements, improved surgical techniques of handling blood vessels, prevention of clotting by anticoagulant drugs and the development of synthetic replacements for portions of large arteries have made the success and safety of blood vessel surgery possible.

o Surgical replacement of damaged heart valves is now generally possible to correct heart valves deformed or damaged by rheumatic heart disease, arteriosclersis, or heart valve infections. Research support from the Institute has helped to perfect the surgical procedures and to develop improved artificial heart valves.

o Coronary bypass surgery to improve the blood flow to the heart muscle by creating a vein graft to bypass coronary arterial obstruction is now a common surgical procedure that evolved from a number of early research experiments on animals, particularly in dogs. The combined techniques which made possible the diagnosis of coronary arterial obstructions by arteriography, procedures that made blood vessel surgery possible and direct operations on the heart with low risk have resulted in widespread availability of this surgical treatment for selected types of coronary artery disease.

o Heart-lung machines, which made possible the maintenance of circulation to the brain and other vital organs bypassing the heart, were key developments that made prolonged surgery on the heart possible. The heart-lung machines were a direct product of Institute heart research support.

o Artificial parts to replace portions of the aorta, iliac, or femoral arteries have emerged from years of research going back to

1952. A variety of synthetic tubes of different sizes and likeness to the aorta or other large arteries are now being produced for surgeons to use for replacement of aneurysms or obstructions of such major blood vessels. The synthetic parts have been specially developed to be compatible with the body and blood.

o Left ventricular assist devices have been developed for short term use in critically ill patients with failing hearts through Institute support.

o Cardiac pacemakers have been brought to improved reliability for long term use to maintain heart beat in patients with heart conduction defects as a result of some Institute support.

o Echocardiography which now provides a noninvasive method using ultrasound to diagnose heart valve damage and abnormalities of heart movements has had direct Institute funding support.

o Intracardiac electrodes which can be inserted into the heart to diagnose complex abnormal heart rhythms have resulted from cardiovascular research support.

o Major risk factors for coronary heart disease have been identified through Institute support and provide a promising potential for methods of prevention. The knowledge concerning the risk factors of elevated cholesterol, elevated blood pressure, obesity, cigarette smoking, diabetes, and lack of physical activity is now being widely applied by physicians in advising patients who are at increased risk of developing coronary heart disease.

o Lipoprotein fractions have been defined by Institute research support making more precise the measurement of blood cholesterol levels and the associated risk of coronary heart disease. Separate cholesterol containing lipoprotein fractions have been defined and are now easily measured. Research through the Lipid Research Clinics has standardized laboratory methodology that has now become widely established for clinical as well as research use. Diagnosis of familial hyperlipoproteinemias is now possible and widely established. More specific therapy can be planned on the basis of such diagnosis.

o High density lipoproteins have been found to have some protective role in coronary heart disease in contrast to low density lipoproteins which are associated with increased risk of developing coronary heart disease. These research findings are now receiving major attention in relation to potentials for prevention.

o Risk factors in the elderly have been identified through Institute research and this has changed concepts about the potential for prevention of coronary attacks in persons into the ages of 70 to 80.

o Radionuclides in the determination of the extent of damage of the heart from a heart attack have resulted from earlier research use of such nuclides in Institute supported research centers.

o New diagnostic tests for acute myocardial infarction have been developed through research support. Enzyme tests that detect heart

muscle damage are now widely used. Continuous ECG monitoring now automatically detects life threatening abnormal rhythms.

o Medical treatment of abnormal heart rhythms resulting from acute myocardial infarction has improved markedly as a result of better understanding of such arrhythmias from research. Evaluation of drugs for the treatment of serious rhythm abnormalities has been carried out under Institute sponsored research and has provided better knowledge for treatment.

o Medical treatment of shock during acute myocardial infarction has been studied in several medical institutions and in Specialized Centers of Research. Extensive research in animals has provided knowledge that has been applied in patients to improve the medical treatment of coronary shock by oxygen therapy and drugs improving heart function.

o Limitation of infarct size from acute myocardial infarction has been a special focus of Institute supported heart research. Findings from this research have been encouraging enough to undertake clinical trials to determine the effectiveness of hyaluronidase and propranolol, two drugs that may have value in the early treatment of acute myocardial infarction.

o Lipid lowering drugs widely being prescribed for the long term treatment of patients after their myocardial infarction have been shown to be of no value in the five year Institute-funded Coronary Drug Project. More important than cholesterol level in determining length of survival following myocardial infarction were factors related to the heart itself, such as presence of heart enlargement, congestive heart failure and presence of heart rhythm abnormalities. Substantial costs of drugs for unnecessary treatment of coronary patients are now being saved by the findings from this research. Greater attention to the management of the heart abnormalities is now recognized to be needed.

o Early hospital discharge of patients with uncomplicated myocardial infarction has been found to be safe in a further Institute funded research project. This provides greater encouragement to physicians in practice and to patients to avoid prolonged hospitalization when cardiac evaluation reveals that a shorter hospital stay is possible for selected patients if the home situation is favorable for further convalescence.

o Hypertension treatment by antihypertensive drugs has improved markedly since 1950 with important conributions from Institute supported research. Several research groups supported by the Institute have been important contributors to the rapid development, evaluation, and testing of the family of different drugs that have emerged for treatment of hypertension.

o Routine therapy for essential hypertension progressing from increasing doses of single antihypertensive drugs to combinations of two or more drugs having complementary action is now widely practiced to achieve optimum levels of blood pressure control. Therapy evaluation resulting in this stepped care management has been funded by the Institute.

o Risk factors for stroke have become defined from epidemiological studies supported both by the NHLBI and NINCDS. Recognition that both the levels of systolic as well as diastolic blood pressure are of clinical importance has lead to changes in clinical management. Other factors such as obesity, increased alcohol intake, and low serum cholesterol are findings from research that will have increasing usefulness in prevention.

o Emergency medical care for victims of heart attack has been improved significantly as a result of research on cardiac resuscitation sponsored by the Institute. The findings from research are now the basis for many active community programs sponsored by both official and voluntary health organizations, particularly the local affiliates of the American Heart Association.

Lung Diseases

o Improved management of bacterial infection in infants...Bacterial infection is a significant cause of illness and a contributory cause of death in neonates with respiratory distress syndrome. Such infection has been difficult to manage and often does not respond to antibiotics. Colonization of infants with a carefully selected nonvirulent strain of alpha streptococci can be done with minimal risk and is very successful in preventing serious infections, representing a major advance toward prevention and control of one of the primary causes of morbidity and mortality in infants with respiratory distress syndrome.

o An advance in lung disease detection...A method to determine continuous distributions of ventilation-perfusion ratios (the ratio of ventilation to blood flow), has been developed which represents an advance in understanding lung gas exchange in healthy and diseased lungs. The technique gives the amount of blood flow to unventilated lung (shunt) and also indicates the approximate amount of blood flow to lung units having specific ventilation-perfusion ratios. Since this technique can determine the continuous distribution of ventilation-perfusion rations, it can be used to detect the subtle signs of early lung disease.

o Early diagnosis of pulmonary edema...A new noninvasive method for the diagnosis of pulmonary edema has been developed. The method uses imaging and counting devices to measure the rate of accumulation for a radioactive labeled protein in the lungs. Since the test measures accumulation rates rather than total accumulation, it is particularly useful for early diagnosis of pulmonary edema.

o Smoking and lung disease...Identification of presymptomatic patients: A collaborative demonstration program has shown that there is a definite relationship between smoking and lung function abnormality, the most impaired lung function being observed in the heaviest smokers. On the other hand, no relationship was found between the presence of respiratory symptoms and abnormal pulmonary function. Thus, it is clear that pulmonary function tests are more useful than symptoms in detecting a smoker's risk of developing chronic obstructive pulmonary diseases. It has now become clear to pulmonary physicians that pulmonary function tests must be used to

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detect a smoker's risk of developing chronic obstructive pulmonary disease.

o Management of adult respiratory distress syndrome...Blood gas measurements: Essential to effective management of adult respiratory distress syndrome, are methods that permit rapid and continuous monitoring of physiologic changes, and particularly of arterial blood gases. New methods have been miniaturized, and compatibility with blood improved.

o The use of extracorporeal membrane oxygenators in patients with acute respiratory failure...Results of a clinical trial: In 1973, a clinical trial was initiated to evaluate the use of the extracorporeal membrane oxygenator for the treatment of patients with acute respiratory failure. Upon completion of the program this past year, it became clear that this treatment fails to increase survival rates over those achieved with conventional care, illustrating the value of evaluating new therapies before they are promoted for general use.

o Therapy for respiratory distress syndrome of the newborn...Continuous positive airway pressure: An effective therapy for respiratory distress syndrome in the newborn has resulted in a survival rate of up to 90 percent in some studies (up from 20 percent a decade ago). The therapy is known as CPAP—continuous positive airway pressure. A pressure above atmospheric level is maintained at the airway opening throughout the respiratory cycle, keeping the lungs expanded and assuring an adequate supply of oxygen to the infant with immature lungs.

Blood Diseases and Blood Resources

o Prenatal diagnosis of sickle cell disease: Research in one of the Comprehensive Sickle Cell Centers has resulted in a simpler and easier method for the prenatal diagnosis of sickle cell disease. With this method, there is no direct interference with the fetus. The investigator who developed this diagnostic technique found a genetic marker that is linked with the gene that controls S-hemoglobin synthesis. The marker is present in about 80 percent of those who have S-hemoglobin, which makes it possible to diagnose, by the use of only cells from the amniotic fluid, S-hemoglobin in the fetus in about 75 percent of at-risk pregnancies.

o Treatment of Cooley's anemia in children: Clinical investigations supported by the NHLBI led to the finding that the combination of iron chelation therapy combined with blood transfusion therapy started early in children with thalassemia could prevent most complications of this disease. The Institute was also instrumental in obtaining FDA aproval for continuous use of this drug (desferol) in the treatment of thalassemia and in the pending approval of a means for subcutaneous administration of this chelating agent.

o Antithrombotic drugs: Studies supported by the Institute have provided the basis on which two antithrombotic drugs can be rationally administered. Work in the early part of this decade showed that type anticoagulant action of heparin occurs as the result of dramatic increase in the rate of inhibition of thrombin, factor Xa,

and other clotting factors by antithrombin III. Aspirin has been shown to exert its antithrombotic action by inhibition of the platelet cyclooxygenase, which acts as a step in the production of thromboxane, a potent platelet-aggregating agent.

o Prolongation of the shelf life of whole blood: Institute supported studies have documented the efficacy of adenine in increasing the effective shelf life of whole blood. The addition of adenine to stored blood was recently approved by the BoB, FDA. It now effectively allows the extension of the shelf life of stored blood from 21 to 35 days. A valuable asset to our limited blood resources.

CENTERS

Question: Dr. Levy, what is the total amount of money in your fiscal 1980 budget which will fund centers programs within your Institute?

Answer: In pursuing the attainment of the goals of the National Heart, Blood Vessel, Lung, and Blood Program, the NHLBI follows a coordinated program strategy comprising a logical progression of activities from basic research on fundamental life processes and mechanisms to practical demonstrations of the clinical applicability of new findings. Many of the disease problems which comprise the Institute's mandate are of such a magnitude and complexity that their solution requires the coordinated efforts of a number of research institutions, a diversity of scientific and technical disciplines, and a range of research approaches. To provide a framework within which such coordinated efforts can take place, the NHLBI has utilized, where appropriate, research mechanisms designed to advance the state-of-the-art of disease prevention and treatment in specified disease areas. NHLBI-supported centers include Specialized Centers of Research, National Research and Demonstration Centers, and Comprehensive Sickle Cell Centers. Funds included in the 1980 budget provide for:

National Heart, Lung, and Blood Institute
(Dollars in thousands)

Centers:	1980 No.	1980 Amount
Specialized Centers of Research (SCOR)		
Arteriosclerosis	8	$10,447
Hypertension	4	5,626
Ischemic Heart Disease	11	13,000
	23	$29,073
Pediatric Pulmonary	8	$ 4,845
Chronic Airways Disease	4	3,088
Fibrotic Diseases	4	3,311
Pulmonary Vascular Diseases	3	1,666
Respiratory Failure	3	2,273
	22	$15,183
Thrombosis	3	$ 3,667
Total, SCOR	48	$47,923
National Research and Demonstration Centers		
Heart	1	$ 4,094
Lung	1	1,312
Blood	1	890
	3	$ 6,296
Comprehensive Sickle Cell Centers	10	$11,312
Total, Centers	61	$65,531

Specialized Centers of Research:

The program is designed to complement--but not duplicate--other research programs including program projects supported by the Institute. It fosters a concerted research effort solicited by NHLBI, but independently developed by outside investigators, involving both clinical and basic disciplines, directed toward the prevention, diagnosis and treatment of diseases identified by the Institute. Envisaged as a coordinated activity, the SCOR program encourages and facilitates exchange of ideas and information among participating centers with mutual interests. In this sense, each SCOR program constitutes a national network.

National Research and Demonstration Centers:

The National Research and Demonstration Centers (NRDC) Program responds to the need for a mechanism which is designed specifically to integrate and coordinate a broad range of research, education, and demonstration activities targeted on a particular disease. NRDCs are designed specifically to bridge the gap between fundamental application of research results in health care and in the prevention of disease.

An NRDC is a national resource dedicated to collaborating with the NHLBI to translate, rapidly and effectively, appropriate results of research into health care and to demonstrate applicability in such a way that the particular activity becomes accepted. It is the inclusion of education and demonstrations, and the coordination of these programs with research and training, that sets an NRDC apart from other types of programs.

The Comprehensive Sickle Cell Centers:

The Comprehensive Sickle Cell Centers Program is an integrative mechanism which facilitates the translation and applications of the results of basic and clinical research on sickle cell disease to improved health care at the community level.

Comprehensive Sickle Cell Centers emphasize research, demonstration, counseling, and education in sickle cell disease. These Centers, combine basic and clinical research, clinical trials, clinical applications, training, and community service projects. These Centers have an Advisory Board with representative scientists and physicians from affiliated medical institutions and representatives from community organizations concerned with sickle cell disease and the subject population. In this comprehensive approach to the problems associated with sickle cell disease, the Centers concentrate resources, facilities, and manpower in a coordinated approach to solving the multiplicity of problems related to this disease, bridge the gap between scientific investigations and service efforts, and thereby insure that research findings are most efficiently made available for incorporation into the health care delivery system.

INCREASED LUNG MORTALITY

Question: We have heard in the past couple of years that heart disease mortality has been decreasing, but we find that the mortality from various lung diseases has continued to increase. Why is this and what can be done to reverse this trend?

Answer: Yes, it is true that mortality of chronic obstructive lung diseases continues to increase. The causes of this trend are as yet unidentified. We can however, assume that this is related to smoking habits especially in some population groups in the post war era. These groups have now reached the age (50 to 60) where the chronic lung diseases are most severe.

Our research program includes follow-up studies which will hopefully shed some light on this increase especially with regard to the role of smoking habits. We are actively supporting a broad research effort targeted at chronic obstructive lung disease. We hope that our current research studies on etiology and pathogenesis as well as our efforts to develop and define sensitive diagnostic noninvasive pulmonary function tests will allow for much earlier detection, control and ultimately prevention of this disease.

Question: What programs do you have in conjunction with the Cancer Institute related to lung diseases?

Answer: The Cancer Institute program is exclusively concerned with cancers of the lung. These cancers are also closely related to smoking. Hence, this Institute and ours have developed complementary programs on the effect of smoking and on the lung tissue alteration in response to injury.

CLINICAL TRIALS

Question: Although clinical trials and patient care is an extremely expensive method of research, we, as a Committee, have felt that it is absolutely critical in developing long-range methods of treating the various diseases. Has your Institute initiated any new clinical trials in the past year, and, if so, what areas are they in?

Answer: As I have noted in the past, clinical trials are a key element in our program strategy. They provide the definitive test of therapies, a test that is difficult if not impossible to perform in practice. As you know from my testimony in the past, each year we devote over 50 million dollars to the trials which now cover a broad variety of therapies in heart disease, in lung disease as well as in blood diseses.

Over the past year, we have continued to progress both with our current portfolio of trials and are initiating trials on new topics. I might mention in particular a new trial on the management of patent ductus arteriosus in newborn infants which has recently entered the planning phase. The ductus arteriosis connects the pulmonary artery and the aorta in the fetus allowing the shunting of blood away from the collapsed fetal lungs. In most newborns the patent ductus closes spontaneously at birth. In some infants, however, surgery is required or the heart will fail. The surgery is expensive and though usually successful is not without risk in these delicate newborns. Recently a drug that inhibits protaglandin (endomethicin) has been shown to effect the closure of patent ductus in most newborns. This trial will test the efficacy and safety of drug therapy which, if successful, would eliminate the need for surgery in this condition.

We have also entered new phases in two of our ongoing trials. Our Beta-Blocker Heart Attack Trial (BHAT), to test the effect of propranolol, a beta-blocker drug, on preventing further heart attacks and sudden death in patients who have already suffered a myocardial infarction, has entered its patient recruitment and intervention phase. Still another trial, the Multicenter Investigation of Limitation of Infarct Size (MILIS), a study on drug treatment to minimize the damage to the heart done from heart attacks, has also entered the recruitement and intervention phase.

Of particular note, our trial on aspirin therapy to further secondary prevention of myocardial infarction is nearing the end of its intervention phase; we expect results to be published by January, 1980.

Another trial, the Hypertension Detection and Follow-Up Program will also end its 5 years of patient follow-up this year. This trial to determine the effectiveness of sustained systematic, anti-hypertensive therapy in reducing morbidity and mortality from hypertension was implemented in 14 communities and has involved some

11,000 patients. This trial promises to provide important therapeutic information on such questions as the value of treating mild hypertension and of the role of community treatment centers in reducing morbidity and mortality. The results of both of these trials will be disseminated to the health care practitioner as soon as they become available so that consensus activities important to the translation to regular health care practice can take place expeditiously.

A related project, recently begun, will enable us to understand more fully the effects of clinical trials on medical practice. This project will establish a medical practice profile before the results of the Aspirin Myocardial Infarction Study are published and then assess practice and sources of information at several stages following release of the results. In this way the project will provide us with information to enable us to assess the most effective means for disseminating the trial results.

An effort related to the management of clinical trials is nearing completion. This fiscal year we will conclude a project to determine the potential for improving the operation of the trial coordinating centers, the organizational components responsible for the day to day conduct and analysis of the trial. These centers may account for as much as 15% of the multimillion dollar cost of a trial. The project is expected to provide information to lower the cost of the center operation without sacrificing critically needed management and logistics.

Lastly, I would like to share with you recent reports on the use of clofibrate, a drug studied in our trial, the Coronary Drug Project. We have data that indicates that the use of clofibrate has decreased dramatically, over 50%, from 1975 to 1978. This is very much in keeping with the results of the trial published in 1976 and in 1977. We found the drug to be ineffective in preventing mortality and morbidity in patients who had previously suffered a heart attack and, moreover, the drug was associated with hazardous and unpleasant side effects. We calculate that the decrease in cost to patients from using this drug is greater than $45,000,000 annually. This result reinforces the conviction of our Institute that clinical trials have an important, cost-effective role to play in our research program. I assure you that we will strive to continue to make our clinical trial program as responsive as possible to research and health care needs.

HEALTH SERVICES ADMINISTRATION

Question: Please explain to us the difference between the hypertension program in Health Services and the one which you are conducting. Isn't this another case of duplication of programs in that there are so many different Federal programs that sometimes people don't know which one to turn to?

Answer: The National Heart, Lung, and Blood Institute has been given the responsibility by the Congress of coordinating a National Heart, Lung, Blood Disease and Blood Resources Program. The area of hypertension clearly falls within this mandate, however, many other federal agencies have the responsibility for executing portions of this effort. In this specific case, the Health Services Administration has been delegated by the Secretary the responsibility

of administering a major health care services portion of the hypertension effort. Administration of the funds distributed to the states is the only function the Health Services Administration has been delegated.

The National High Blood Pressure Education Program, which is coordinated by the National Heart, Lung, and Blood Institute, is a broader effort. It is within this broader effort that the Health Services Administration assists in the provision of health care services. They represent one participant in the National High Blood Pressure Education Program. Many other federal agencies are involved, for example: The Food and Drug Administration, the Veterans Administration, the Civil Service Commission, the Health Resources Administration, the Department of Agriculture and the Department of Defense. In addition, many private sector groups, approximately 150 major professional, voluntary, insurance, pharmaceutical, and other organizations participate. The program also relates to approximately 2,000 identified and on-going local community hypertension control programs.

The broad goal of the National High Blood Pressure Education Program is to reduce the number of deaths and illnesses associated with uncontrolled hypertension. Our approach to doing this is a through coordinated educational effort involving the many participants just mentioned. A key ingredient in this program's well noted success is the use of the consensus development process. Under the aegis of this program, the nation developed for the first time among leading professional groups a clear consensus on recommendations for the detection, evaluation and treatment of high blood pressure. Similarly, recommendations have been developed for the education of physicians, nurses and pharmacists in high blood pressure control. Through the consensus process, many questions have been clarified regarding blood pressure control in children, in the elderly and among minority populations. The difficult problem of achieving life-long adherence to a regimen has not been solved, but has been made an approachable problem through this process.

In addition to coordination and management of this consensus development process, the National Heart, Lung, and Blood Institute also supports some related investigations. We have in the past supported a grants program to improve our research knowledge of methods for educating hypertensive patients and enhancing their ability to achieve long-term control of their hypertension. We are currently supporting four contracts with state governments in Connecticut, Maryland, South Carolina and California to test coordinating mechanisms at the local level and to assess the impact of these mechanisms on the outcomes of hypertension control. We are supporting, through contracts, three research projects to test the effectiveness of approaches, and to assess their relative costs, to achieve control programs at the worksite.

At the Institute, we develop mass media education materials and also work with many other organizations who also do this to achieve a well planned and well coordinated effort to inform the public about the dangers of hypertension and the necessity for sustained treatment.

The results of these efforts, and I have given you only a few specific examples of these efforts, are clearly measurable. Since the National High Blood Pressure Education Program began in 1972, we have observed a definite increase in the number of patient visits for hypertension which are up 50 percent from 1972 to 1977. Through a survey conducted on behalf of the Program by the Food and Drug Administration, we know that physicians in large measure have adopted the patient evaluation and treatment recommendations of the National High Blood Pressure Education Program. Community after community has reported significant increases in the numbers of people with high blood pressure who are now aware of their problem and who are bringing it under treatment and under control.

Most important, we have observed some time associated declines in stroke death rates which appear to be related to the Program effort. Since the advent of the National High Blood Pressure Education Program in 1972, stroke deaths have been declining at a rate greater than 5 percent a year.

In summary, the National High Blood Pressure Education Program which we coordinate incorporates the activities of many private and public agencies and organizations. The Program has clearly stimulated both increased and more effective hypertension control activity among community groups and among appropriate federal and local government agencies. More patients are being seen, appropriately treated and are achieving control of their blood pressure. And most important, we appear to be contributing significantly to the prevention of premature death among hypertensive patients.

STROKE

Question: Last week's news stated that strokes are down dramatically. Can you elaborate on this, and explain your role in this?

Answer: Age-adjusted cardiovascular mortality rates have declined almost 32% over the past 30 years. In the last 10 years, however, the decline has accelerated precipitously accounting for over 2/3 of the total 30 year decline. This decline is seen in both sexes, in the white and non-white and in every age decade band from the 2nd to beyond the 8th. Not only have death rates declined but despite an aging and ever increasing population the total number of cardiovascular deaths fell below 1 million in 1975 for the first time in almost a decade and the estimated 960,000 cardiovascular deaths in 1977 represent the lowest level since 1963. During the nine years since 1968 coronary heart disease mortality rates (the leading cause of death in the U.S.) declined 23 percent. For stroke the decline was even greater, 32 percent.

Stroke still ranks as the third most common cause of death in the United States (an estimated 182,840 deaths in 1977). It is also the cause of disability for an estimated 1 million Americans. A downward trend in stroke mortality has been apparent for more than 50 years. Of importance is the fact that the downward trend in stroke death rate appears to have accelerated. In recent years, death rates for stroke have declined more rapidly than for any other component of cardiovascular mortality. In the 1940's and 1950's stroke mortality

declined less than 1 percent per year, in the 1960's, 1.7 percent per year and since 1972, 5 percent per year. Though sizable geographic differences have been noted in the past in stroke death rates in the United States, rates in all regions have fallen in the last 15 years with rates tending to converge with less variation from region to region. All 4 major age-sex-color groups have shared in the stroke decline but the decline by sex for non-whites (primarily blacks) is relatively and absolutely greater than for the comparable white population. In fact the 48.5 percent decline in non-white females age 35-74 over the period 1960-1975 represents a fundamental change in the pattern of this disease.

Finally, comments about our apparently changing stroke morbidity and mortality would hardly seem complete without some speculation as to cause. Certainly management and rehabilitation of the stroke victim has improved greatly. If stroke incidence is down as it apparently is, we must give even more attention to risk factors and prevention. In this regard, it is important to note that data from the Framingham study indicates a 2 to 17-fold greater contribution to stroke by hypertension than by other risk factors. Moreover, the Veterans Administration Cooperative Study leaves little doubt that treatment of at least moderate and severe hypertension can prevent stroke. To the extent that hypertension causes stroke and stroke mortality, its impact should be declining. Not only has effective hypertension therapy been available for the past 20 years and evidence of its efficacy vis-a-vis stroke been clear for almost 10 years, but hypertension awareness, detection and control has increased greatly due in good part to the nationwide voluntary, private and federal sector NHLBI coordinated National High Blood Pressure Education Program which began in 1972.

Overinterpretation of the striking temporal relationship between hypertension control and stroke decline would be folly at present since many other risk factors, environmental conditions and treatment approaches have changed over the past 30 years. Overlooking the present benefits and potential future gains through even more effective hypertension control would be equally foolish.

National Institutes of Health

STATEMENT OF LEON M. SCHWARTZ, ASSOCIATE DIRECTOR FOR ADMINISTRATION

ACCOMPANIED BY:

DONALD S. FREDRICKSON, DIRECTOR NIH
H. ROY ROUTT, JR., BUDGET OFFICER, OFFICE OF THE DIRECTOR, NIH
ROSS HOLLIDAY, DIRECTOR, DIVISION OF ENGINEERING SERVICES, NIH
NORMAN D. MANSFIELD, DIRECTOR, DIVISION OF FINANCIAL MANAGEMENT, NIH
KENNETH S. LEVINE, DEPUTY ASSISTANT SECRETARY FOR LEGISLATION
WILFORD J. FORBUSH, DEPUTY ASSISTANT SECRETARY, BUDGET

BUDGET REQUEST

Senator Schweiker. OK. I think we will proceed, then, to the Office of Director.

Mr. Leon Schwartz, who is the Executive Officer of the National Institutes of Health, will be the next witness to testify.

Your budget is $21,062,000 compared to last year's level of $20.4 million.

Mr. Schwartz, do you have any comments to make before questioning?

PREPARED STATEMENT

Mr. Schwartz. With your permission, Mr. Chairman, I would like to submit my statement for the record. I will be happy to respond to any questions.

Senator Schweiker. Without objection, it is so ordered.

[The statement follows:]

STATEMENT OF LEON M. SCHWARTZ

Mr. Chairman and Members of the Committee:

It is a pleasure to appear before this committee to discuss the budget for the Office of the Director of the National Institutes of Health.

Funds appropriated to the Office of the Director provide for the central executive direction and management of the National Institutes of Health including some very essential support services.

Specifically, this appropriation includes support for (1) the Director and his immediate staff, and the office responsible for equal employment opportunity, program planning and evaluation, public and scientific communication, protection from research risks, and (2) management support activities, budget, accounting, personnel, management analysis and review, and contracts and grants.

The Immediate Office of the Director includes principal associates of the Director who provide assistance in policy development and decisions including the coordination of intramural and extramural research programs of the Institutes and Research Divisions and the programs of the National Library of Medicine. Staff offices responsible for program planning and evaluation and for public and scientific communications support the Director in carrying out these responsibilities.

The management and program services financed by this appropriation support the overall management of the National Institutes of Health and provides a number of services to individual institutes and divisions. It is expeditious and economical to provide management and program services on a consolidated basis since most of the National Institutes of Health is located within the Bethesda, Maryland area. The services financed through this appropriation include overall development of financial policies and procedures, and budget formulation, execution and analysis; position classification and salary administration, activities to assure equal employment opportunities, and a wide range of other personnel management services for over 11,000 employees; contracts and grants management services relating to approximately 24,000 projects; and management studies and reviews which promote economies and efficiency of operations and insure effective application of policy and procedural controls throughout all of the operating components of the National Institutes of Health.

The Office of the Director provides the overall leadership in implementation of Congressionally mandated programs, such as dissemination of research results, protection from research risks, fair information practices, as well as Executive Branch priorities in civil rights compliance, and equal employment opportunity programs. Through the Office for Medical Applications of Research, NIH plans to improve the translation of the results of biomedical research and development pertinent to health care into knowledge which can effectively be employed in the practice of medicine and pbulic health.

DIRECT OPERATIONS

The direct operations activity of this appropriation provides for the direction, operation, and administration of NIH accounting functions as well as certain personnel activities, and includes payment for centrally furnished services for all Offices and Divisions of the Office of the Director. The accounting functions include voucher auditing,

payment of invoices, accounting and financial reporting and analysis. Personnel functions include counseling, training and the processing of more than 20,000 requests for various personnel actions during the fiscal year.

Appropriation Request

Mr. Chairman, the appropriation request for the Office of the Director is $21,062,000 for 1980, an increase of $635,000 over the 1979 level of $20,427,000. The requested increase of $635,000 is to support the NIH share of the redesign and implementation of a Department-wide grants and financial system.

Buildings and Facilities

The Buildings and Facilities appropriation provides funds for design, construction, repair and improvement of facilities for the National Institutes of Health.

For Fiscal Year 1979 we are presenting for your consideration a proposal to rescind the $37 million appropriated in fiscal year 1979 for the construction of an intramural research facility for the National Institute of Child Health and Human Development (NICHD).

The current research programs of the NICHD are consider to be of highest quality. We have every reason to believe that this record will be sustained without a new facility. While locating all of the research programs in a new single facility may serve to be more convenient for those conducting cooperative studies, the advantages of such a consolidation proposal do not warrant the expenditure of $37 million.

The Federal commitment to the research programs of the NICHD has been recognized. In 1979, the Institute has available an increase of $24 million in program funds above the 1978 level.

The commitment to maintain a strong biomedical research program continues. I can assure you, Mr. Chairman, that the high quality of our research programs to improve the health and well-being of mothers and children will endure without this new facility.

In Fiscal Year 1980, we are requesting $3,250,000 for the following:

Repairs and Improvements - Plant	$1,250,000
Repairs and Improvements - Program	2,000,000

I will discuss these briefly.

Repairs and Improvements - Plant

1980 Budget Request $1,250,000

These funds are needed to continue the program of major repairs and improvements to the various electrical, mechanical and structural components of the physical plants at Bethesda, Poolesville and Baltimore, Maryland; Hmailton, Montana; Research Triangle Park, North Carolina; and other field stations for which NIH is responsible. The physical plants are quite extensive and many of the buildings and supporting facilities have been in service for nearly four decades. This is a recurring need of providing for the care and upgrading of the physical plants.

Repairs and Improvements - Program

1980 Budget Request $2,000,000

These funds are also required to continue the financing of alterations directly related to program needs which must be characterized as capital improvements. The work includes changes in physical facilities to accommodate revisions and new initiatives in research efforts.

BUDGET INCREASES

Senator SCHWEIKER. Since 1970, the budget of the Office of the Director has grown from $7 million to a proposed level of $21 million. I think it is safe to say that there are very few Institutes that have tripled in the last 10 years.

To what do you attribute this increase, and what are your expectations in the future?

Mr. SCHWARTZ. In analyzing the increase, Senator, what we find is that the level of personnel has only increased 12 percent over a 10-year period.

What we are reflecting in the OD budget are a number of areas that cut across all of NIH.

Senator SCHWEIKER. You say the level of personnel has not changed.

Mr. SCHWARTZ. Has not changed significantly.

Senator SCHWEIKER. In 10 years.

Mr. SCHWARTZ. That is correct. The increase in cost is due to salary levels, and a number of activities.

Senator SCHWEIKER. That wouldn't be three times, though. As I read this, not many people have had their salaries tripled since 1970.

Dr. FREDRICKSON. The Director hasn't had his salary tripled.

Senator SCHWEIKER. Neither has the Senator.

Mr. SCHWARTZ. If you analyze the cost, you will find that 20 percent of the increase over this period of time is attributable to Federal salary increases.

OVERHEAD COST

You will also find that there are a number of items, such as our fair share of the overhead costs that have gone up about 14 percent.

Senator SCHWEIKER. How much?

Mr. SCHWARTZ. Fourteen percent of the increase.

Senator SCHWEIKER. Twenty percent, is that your biggest segment of the cost increase?

Mr. SCHWARTZ. Yes, sir. The next figure is overhead items. I would point out that the cost of energy at NIH has gone from $2 million in 1970 to something in the order of $12 million.

Senator SCHWEIKER. Who allocates those overhead figures?

Mr. SCHWARTZ. It is allocated by a formula that has been developed. On the basis of energy, it is the number of personnel that each appropriation has.

Senator SCHWEIKER. What is next?

Mr. SCHWARTZ. There are a number of items that are in the range of 10 percent. There are activities associated with new items, such as legislative requirements dealing with research safety.

We have consultants and commissions. The cost of commissions in the last few years has increased considerably.

Senator SCHWEIKER. I thought you abolished all the commissions.

Mr. SCHWARTZ. This also includes congressionally mandated commissions.

PAY INCREASE

Senator SCHWEIKER. That is fine. OK. For the Office of the Director, $784,000 is being requested in the pay increase supplemental.

Why is this the only program in all of NIH which is asking for an increased amount to cover the pay costs of last year?

Mr. SCHWARTZ. The Office of the Director consists largely of staff costs. So our budget is about 80 percent related to personnel costs, and there really are no opportunities to reprogram funds from other areas to pay salary increases. Whereas, most of the other organizations do have some additional extramural funds that can be reprogramed.

REDUCTION IN APPROPRIATION REQUEST

Senator SCHWEIKER. Will you supply for the record one or two areas, for the chairman, within the Office of the Director that could be eliminated in a 5-percent cut?

Mr. SCHWARTZ. Yes, sir. We have thought about it, and will be glad to supply that information.

Mr. FORBUSH. I might also add that the total cost is $1 million, and they are absorbing about $300,000 of this total in the appropriation for the Office of the Director.

PROGRAM ENHANCEMENT

Senator SCHWEIKER. All right. Now, let me give you a plus question.

On the other side, if there were programs, in fact, that could be done, but only with more funding, what would you recommend for the Office? Is there anything on the plus side that we ought to think about?

Mr. SCHWARTZ. Specifically, I think we would probably enhance policy development in NIH, in the areas of program policies, and contract and grant management.

Senator SCHWEIKER. The committee would like to have all transcripts, as well as questions for the record, back in approximately 7 days, so the committee can meet its time schedule.

SUBCOMMITTEE RECESS

We are now going to adjourn the subcommittee until 2 o'clock, when we will begin with the dental section.

[Whereupon, at 12:40 p.m., Wednesday, February 28, the subcommittee was recessed, to reconvene at 2 p.m., the same day.]

(AFTERNOON SESSION, 2:05 P.M., WEDNESDAY, FEBRUARY 28, 1979)

NATIONAL INSTITUTE OF DENTAL RESEARCH

STATEMENT OF DR. DAVID B. SCOTT, DIRECTOR

ACCOMPANIED BY:

DR. DONALD S. FREDRICKSON, DIRECTOR
NORMAN D. MANSFIELD, DIRECTOR, DIVISION OF FINANCIAL MANAGEMENT
KENNETH S. LEVINE, DEPUTY ASSISTANT SECRETARY FOR LEGISLATION
WILFORD J. FORBUSH, DEPUTY ASSISTANT SECRETARY, BUDGET

1978 APPROPRIATION AND 1980 BUDGET REQUEST

Senator SCHWEIKER. Our next Institute is the National Institute of Dental Research. The Director is Dr. Scott. The President is requesting $66,118,000 for fiscal year 1980. This is barely $900,000 more than was provided in the last budget.

PREPARED STATEMENT

Dr. Scott, if you have a statement, please summarize it and we can go on with your questions.

Dr. SCOTT. Mr. Chairman, we do have an opening statement that we would like to submit for the record.

Senator SCHWEIKER. We will put it in without objection.

[The statement follows:]

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STATEMENT OF DR. DAVID B. SCOTT

Mr. Chairman and Members of the Committee:

I appreciate the opportunity to appear before this subcommittee to review the programs of the National Institute of Dental Research.

Dental Caries

Our National Caries Program continues to pursue all leads toward the prevention of dental caries through increasing the resistance of teeth to decay, modifying caries-producing diets high in sugar and combatting the effects of harmful decay-causing bacteria.

Water fluoridation is still the best way to decrease the caries attack. However, for those communities that do not have the benefit of fluoridation, other ways of providing protection are needed. Last year, we completed two years of nationwide demonstrations of school-based fluoride mouthrinsing. This preventive program is low in cost, it is well accepted by parents and children, and substantial reductions in caries incidence can already be detected. The national media reported these results extensively after a press conference in July. We have received thousands of requests for advice from communities interested in school-based fluoride programs and expect these to become available within the next few years to many of the 25 million children in non-fluoridated areas.

Last year, we reported early results from animal tests of a device that can be attached to a tooth and will release precise amounts of fluoride or other preventive agents for as long as six months. We expect to begin human trials shortly.

Research on a caries vaccine was given impetus by the finding that antibodies against certain oral streptococci could be detected in the saliva of humans who swallowed a vaccine made from killed organisms. The feasibility of inducing an immune response similar to that achieved in our animal experiments is thus confirmed in humans. Whether this route of vaccination is the preferred one and which vaccine will produce the best response are among the many questions to be resolved before human clinical trials can be contemplated.

Because of current interest in the relationship between sugars and oral health, a reliable method to identify highly cariogenic foods is needed urgently. In a new screening procedure rats are given a basic diet containing all the required nutrients by stomach tube, and the food item being tested is fed by mouth at frequent intervals during the day from an automatic dispensing machine. A snacking pattern is thus simulated and any resultant dental caries can be attributed solely to the test food.

Periodontal Diseases

Two out of three Americans suffer from periodontal diseases and about 25 million have lost all their teeth largely as a result of them. Our research includes studies of the causative bacteria and their by-products, the cascade of immunologic responses activated in the host, and the efficacy of various treatment procedures. Attention is given to the cellular and chemical mechanisms involved in inflammation and tissue destruction. New evidence suggests that impairment of white blood cells (leukocytes) that serve as the first line of defense against disease may be caused by oral bacteria. This may offer a partial explanation for the increased severity of periodontal diseases reported in

diabetics. Related information has come from the observation that diabetic rats recovered more slowly from periodontal surgery than normal controls and that protective activity of their periodontal leukocytes was a third less. These findings are the first to show altered leukocyte function at the local disease site. Analogous studies will soon be carried out in humans.

Continuing investigations of connective tissues are essential to full understanding of periodontal diseases. Information on the role of immunological factors in regulating connective tissue metabolism may make it possible eventually to inhibit the tissue destruction which leads to gradual loosening of teeth.

Efforts to improve treatment methods are also continuing, especially at our clinical periodontal research centers.

Craniofacial Anomalies

In this area we include studies of birth defects, malocclusion, and various acquired defects. In our intramural laboratories, we have developed model systems to screen agents suspected of causing birth defects. These permit a rapid and sensitive identification of potentially hazardous materials, and they are also capable of distinguishing teratogens with different actions.

Dilantin, the principal drug used to treat epilepsy, can cause human birth defects, including cleft lip and palate. Animal studies are beginning to offer a partial explanation for this effect, which appears to result from genetic impairment in the ability of some mice to metabolize the drug.

Restorative Materials

Developing new materials for dental restorations and appliances, and refining existing ones, are continuing activities. Recent findings have given us a new understanding of the corrosion that occurs in the metal alloys widely used in dental practice. We are also working on strengthening the plastic composite filling materials, so that their usefulness, thus far limited to anterior teeth, can be extended to the more highly stressed posterior teeth.

A promising new material, silphenylene, has been developed for maxillofacial prostheses where accident or disease has caused severe disfigurement. It looks and feels like skin and will be used in clinical trials.

For a number of years we have supported extensive laboratory investigations and beginning clinical studies on the design and biological acceptability of artifical implants as replacements for natural teeth. At the same time the use of implants in patients by a substantial number of practitioners has been increasing. In light of current interest in technology assessment, it became evident that a review of this area would be timely. Last summer we sponsored a consensus development exercise on the benefits and risks of dental implants. The working group concluded that none of the four types of implants under consideration was ready for unrestricted use and conversely, none was totally unsuitable. Participants agreed that more clinical research on the whole field of dental implants is necessary. Based on the experience we have already had and on the consensus findings, we are planning a series of clinical trials in the next few years.

Soft Tissue Diseases and Nutrition

Canker sores, fever blisters, and oral cancer affect thousands of people every year. We are looking for ways to prevent or to detect and treat these diseases. Studies on the early detection of asymptomatic oral cancer have yielded important information emphasizing the need to revise diagnostic procedures to include investigation of the entire throat.

Many of our nutrition studies have implications beyond the effect of diet on dental health. For instance, it has been found that high protein diets cause increased calcium excretion in both animals and humans. It is important to look into this because prolonged use of high protein diets may reduce the mineral content of the bones.

Pain Control and Behavioral Studies

An estimated 11-13 million Americans cite fear as the primary reason for avoiding dental treatment. Since fear often begins with a child's initial dental experiences, investigators are studying anxious or disruptive behaviors during early dental visits. Other investigators are measuring and treating dental fear in a controlled laboratory setting.

Oral diseases are strongly influenced by individual and societal behaviors such as dietary choices, personal hygiene, compliance with treatment, and adoption of preventive measures such as community water fluoridation. Our research in these areas is being expanded.

In our own laboratories, we are studying the biology of the pain experience. We have identified specific nerve cells in the spinal cord that relay pain information to the brain where it is translated into conscious sensation. The same region of the spinal cord receives input from descending pain-suppressing pathways from the brain, which are mediated through secretion of chemicals similar to morphine and other opiates. Further understanding of these pain-suppressing pathways should provide insights for development of new pain control methods.

Dissemination of Information

The Institute has stepped up its dissemination of information. Activities that began with announcement of the findings from the fluoride mouthrinsing program will expand as further results become available.

A campaign to inform children, parents, and educators of the dental problems associated with snacking on sugared foods is beginning. Several public service television spots, publications, and an exhibit are in planning and production stages.

This year a leaflet outlining proper eating habits, hygiene practices, and the need for professional care was published in Spanish and English. Mother and expectant mothers constitute the primary audience and over one-half million copies have been distributed through supermarkets, neighborhood health centers, and prenatal and baby-care classes. Another publication outlining techniques for self-care, "RX for Sound Teeth," has been very popular - nearly 400,000 copies have been distributed in one year.

Exhibit on periodontal diseases and oral cancer have been shown widely at professional meetings throughout the year, as has one on the

behavioral aspects of oral disease. Several new publications were made available to practitioners, researchers, educators, and students. Subjects include sweeteners and dental caries, taste, alternatives to gold alloys, the cranium of the new born infant, rod anode x-ray sources, and others.

Budget Request

In conclusion, the budget request for the National Institute of Dental Research is $66,118,000. I shall be pleased to try to answer any questions and supply additional information desired for the record.

DENTAL DISEASE

Dr. SCOTT. By way of a quick progress report or summary, may I just mention that a good deal of what Dr. Upton said this morning in his prelude, regarding the highlights of his program, applies to ours, also, in that the search for truth in science is a long one. We, too, have to face the need for basic facts in our problem area.

We differ somewhat from other Institutes, in that we deal almost exclusively with very highly chronic diseases that affect 98 percent of the public. We have to find some practical way to cope with these diseases, which are not overly dramatic in their effects, although economically they are, and in the acute phases they are.

Perhaps our most outstanding practical achievements have been made in the national caries program. This is due to the fact that the basic science background is farther advanced than in most other areas. With that view, most of our applied research, including contracted studies and clinical trials, is done in the area of caries.

CARIES PREVENTION

In the realm of caries prevention, as a practical matter, we have been conducting a series of demonstrations on fluoride mouth rinsing. These are now completed in the first go-around and will be continued only in a half a dozen instances of studies with older children in the teenage group.

There was a large conference last summer relative to the outcome of these demonstrations. The results were very encouraging, from the standpoint of cost effectiveness, community participation, which incidentally was almost 90 percent, and potential for continuation at the expense of the community itself from this point on. All of those were favorable.

The publicity was good, and we have since had quite an upsurge in the demand for information from communities that are asking for help in starting programs of that type. We estimate that something like 8 million more children are already receiving this benefit who did not receive it before these programs began.

We are also very much interested at the moment in trying to find out where prevention is going in general. We do not have the benefit of death records or any such morbidity or mortality statistics that we can deal with. We have to depend entirely upon survey material, much of which is either inadequate, nonexistent, or obsolete at best.

For that reason, we have just advertised a contract, and now have the bids in, to do what we think will be a quite definitive survey of the position in the United States of the population with respect to dental caries. With a good examination technique and a good statistical approach, the results will serve not only as a basis for future work, but also will afford comparison with former studies that have been made, and should tell us just where we are going in prevention at this point in time.

There is evidence from a few individual community studies that have been made that caries is dropping off to some degree and that the missing tooth rate is declining, as characterized by the down trend in the numbers of people who have complete dentures.

It looks as if there is an advance being made in prevention. However, we know that to achieve a very high rate of prevention, we are still going to have to find better methods than we have right now.

DIET

From the standpoint of dietary components, we are still very much interested in doing something about the composition of the diet with regard to sugary foods, and we are also working on methods to try and see which foods may be offenders in the caries process. We know generically that sugar is an offender.

We are developing methods for telemetry in the oral cavity to see what foods do affect the acidity of the dental plaque, and we have developed methods now of feeding animals the dietary essentials by stomach tube and then exposing them to sugar-containing foods directly in the mouth to get an idea of cariogenicity of the test foods. We obviously cannot make such trials in humans. The machines that we use now for test feeding the animals the sugary ingredient, or any test ingredient, will expose animals over a period of time, 17 or 20 feedings a day, for example, much like a snacking pattern will be in the human. We look forward to seeing what we can find out that will help out in this battle against the consumption of sugar.

VACCINE

In line of a vaccine, there is very slow forward progress. A report of interest this year, is that some studies have been done on human volunteers, who have swallowed a killed streptococcus vaccine and developed antibodies in their saliva. This resembles what we found in animals before and gives us much heart in moving forward to try to develop a useful vaccine against cariogenic bacteria that can be tested clinically.

IMMUNE RESPONSE

Moving on to periodontal disease, the immune response is still high on our list. It has become more and more evident that the loss of supporting bone and damage to soft tissues is traceable to some form of immune reponse, a response to bacterial infection. So basic information is being collected now that we never had access to some few years ago.

PREVENTIVE METHODS

Senator SCHWEIKER. Is there any hope in sight about what we can do about it?

Dr. SCOTT. So far, in line of prevention, not much, unless you are willing to accept the fact that once we conquer plaque in either caries or periodontal disease, this is a big step. So; yes, if we can make a victory over microbial infection, we are a long way toward prevention.

We still have to improve treatment methods right now in order to cope with much of the existing periodontal disease. We have some very encouraging news from one of our centers, in the line of antibiotic therapy which, as you know, over a long period of time has good and bad sides to it. This group has now worked out a fiber system in which microfibers with varying porosity are packed with tetracycline. Release of the tetracycline through the pores of the fiber can be made to occur at a very slow rate. These fibers are small enough to place right into the periodontal pocket area. With this technique, it has been found that a better level in the tissue can be achieved with about one-thousandth the dose required when the drug is taken systemically. Along the therapeutic line, this is a very encouraging point. Slow release methods in general are being worked on in caries and periodontal disease.

We are also coming along quite well in some basic considerations relative to prevention of craniofacial disease, such as cleft palate and cleft lip. Those diseases can be caused by drug intake, for example, and I refer to certain drugs that are legitimately taken by the patient. Dilantin, used in the treatment of epilepsy, is an example. Using this drug as a test mechanism, we now begin to find the point in the cycle of development of the embryo when the disorder arises. It is apparently a very close point in time, which encourages us to think that through control of medication we can possibly get some prevention into the picture.

We are also moving along in the development of restorative materials and in studies of nutrition and soft tissue diseases. All of these are mentioned in the report which you have admitted for the record.

5-PERCENT REDUCTION

Senator SCHWEIKER. Will you answer the same 5-percent cut question that I've been asking the other directors for the record?

Dr. SCOTT. Yes.

[CLERK'S NOTE.—This answer is included in Dr. Fredrickson's overview testimony.]

SEALANTS

Senator SCHWEIKER. What progress have we made and what technology is available for the use of sealants by dentists?

Dr. SCOTT. Progress in the use of sealants has been made over a period of years, and in the last 2 or 3 years it has been mostly a matter of demonstration and cost-effectiveness studies. Right now the picture is that sealant on about 60 percent of the teeth treated survives a fairly long period of time, up to several years. In teeth where sealant does survive, protection is essentially complete.

Senator SCHWEIKER. What progress are we having with the use of these sealants by practitioners?

Dr. SCOTT. That is what I was alluding to when I mentioned that the cost-effectiveness studies were being made.

It appears to be a technique that is more suited to practitioners under their clinical circumstances, than for field or public health methods, because of the cost of application. The American Dental Association is right now planning another survey to try and see what the current status is in clinical use. We have a notion that usage may be moving more slowly than we had thought.

DISSEMINATION OF INFORMATION

Senator SCHWEIKER. What might you be doing, or the Institute doing, to encourage that?

Dr. SCOTT. We are still promulgating the information to the profession by exhibits at meetings and publications in the scientific or professional journals.

Senator SCHWEIKER. OK.

As you know, the committee has been critical of the Institute's efforts in past years to involve itself to help the programs of dental training schools around the country.

What efforts have you taken in the past year in this area to improve the situation? How specifically are you working with the Center for Disease Control in the health resources in that area?

Dr. SCOTT. I'm not sure I quite understand the question.

Senator SCHWEIKER. I think the question is directed toward coordination between what the Health Resources Administration is doing, and the CDC is doing, and then translating that into dental practice and what your role or spot is, for example, sealants would be one example of that. In other words, if we have a new method, how are we putting that into the training of dentists, in dental schools, extending the curriculum at dental schools to include some of these innovative ideas that we feel saves money or helps the periodontal or cavity problem?

Dr. SCOTT. I think basically one should not sell short the faculties of the educational institutions. Their job is to try to stay abreast of new findings, and that they do. With that in mind, we, of course, keep the findings coming. We circulate the material in workshop reports or books or reprints or bulletins to them. And in addition most of the clinical trials that we have done were conducted at dental schools, or by faculty members. There is continuing contact with the academic organization, with us providing basic information which they incorporate into their programs.

Dr. FREDRICKSON. Senator Schweiker, I would like to add one comment to that question. I think the Dental Institute is unique among all the Institutes at NIH in that it underwrites nearly all of the scientific research of the dental profession, and it does that through the dental schools. If there is to be a scientific base to the dental profession in this country, this Institute has an extraordinary job to do, and does it well by making sure that those schools are teaching scientific dentistry, literally on the cutting edge of an important problem.

QUESTIONS SUBMITTED FOR RESPONSES

[The following questions were not asked at the hearing, but were submitted to the Department for response subsequent to the hearing:]

INFORMATION DISSEMINATION

Question: Last year you mentioned that the Institute had developed two television spots as part of its Public Information Program on the subjects of the relationship between sugar and cavities and dental sealants. Where have these been shown--we have yet to talk to anyone that has seen them. What more are you planning in this important area of information dissemination?

Answer: Last year we reported that we had developed a television public service announcement on dental sealants and that we were preparing another on the consumption of sugary snacks. The dental sealants spot was mailed to over 700 television stations throughout the country, and almost one-third of these stations (an unusually high response rate) reported that they were using the announcement. Many stations asked for additional materials to be used for broadcasting to children. Our spot on snacks is expected to be released next month and will be sent to all 750 stations in the U.S., along with supportive promotional materials. The effects of television announcements and films are difficult to measure, especially when the desired effect is a change in health behavior. We are able to gather information on how many times a film or announcement is shown and to estimate the size of the viewing audience. We do know, for instance, that our 10-minute television film on fluoride mouth-rinsing programs, entitled "Reading, Writing and Rinsing", has been shown by 379 television stations since its release in early 1977. The audience for these showings has been estimated as almost 7 million people.

We plan two or three additional television public service announcements for children and parents on the hazards of frequent snacking of sweets. Along with these, we plan an exhibit, a 30-minute film for possible television use and other showings, several publications, posters and other informational materials directed to children, parents, educators, and others responsible for what children eat and what they know about nutrition.

Question: Could you specifically identify some of the dissemination techniques you use to provide information on dental research to the scientific community, dental practitioners, and the general public? Have you taken any measures to implement a survey process in order to monitor how the dental profession is utilizing the information disseminated by your Institute--in other words, what impact you are having?

Answer: In this area of dissemination techniques to the scientific community, the NIDR sponsors workshops to discuss fundamental research problems, clinical trials, and treatment methods of dental diseases and disorders (i.e., aphthous stomatitis-Behcet's syndrome). We participate in seminars and scientific meetings, publish individual research reports and prepare proceedings of workshops and conferences and present exhibits at major scientific meetings.

For the dental practitioners, we prepare articles on dental research activities for use in dental journals, newsletters and other publications; participate in dental society meetings with speakers and with scientific exhibits concerned with research find-

ings; provide literature on dental research for distribution to dental patients and prepare films showing latest research information on use of fluoride supplements. The NIDR recently sponsored a consensus development meeting concerning the use of artificial tooth implants, the proceedings of which are being disseminated widely.

In addition, the NIDR provides the general public TV-radio announcements with dental health information and publications such as "Good Teeth for You and Your Baby"--printed in both English and Spanish; participates in meetings of health educators with speakers, films, literature, and exhibits; cooperates with journalists to provide their readers with accurate information on dental research studies and on dental health; responds to individual requests for dental health information; and prepares films instructing laymen on use of school-based fluoride tablet and mouthrinsing programs.

The Bureau of Economic Research and Statistics of the American Dental Association conducted a survey a few years ago with NIDR support to determine the use of various preventive methods employed in dental practices. We are now designing a followup survey which we expect will yield valuable information on the degree of change in utilization of preventive procedures, particularly those earmarked by the National Caries Program.

TELEVISION SPOT ON SEALANTS

Question: Last year, you also mentioned that a television spot had been prepared on the subject of sealants. What have you done to follow up on the effect of such direct communications with the public in terms of increasing consumer demand for the technique?

Answer: As mentioned earlier, our television public service announcement on dental sealants has been shown widely throughout the country. We do not have a mechanism for measuring consumer demand for sealants as a direct result of this TV spot or other communications with the public on this subject. We are now planning a survey of practitioners as a follow up to one conducted earlier to determine the kinds of preventive measures in use by dentists across the country. Sealants are among the preventive practices to be included. By comparing these results with those of the earlier survey, we should be able to assess the cumulative results of all the promotional efforts on dental sealants.

NATIONAL SURVEY

Question: In October you announced that the Dental Institute was going to survey the United States for the prevalence of tooth decay. You have requested that a contractor be selected for this. It is my understanding that the contractor would be responsible for the recruitment of examining teams, training and supervision of personnel, travel arrangements, and obtaining local cooperation and parental permission for all examinations. This project appears to be a very expensive way to simply obtain information on the prevalence of a disease. How much do you expect it to cost? Are you working with the National Center for Health Statistics in this project--shouldn't you be?

Answer: The survey we are planning on dental caries prevalence is certainly a large undertaking. But existing data are fragmentary and badly outdated. There is no other mechanism to obtain valid information on the prevalence and trends of this major public health problem, and to evaluate the effectiveness of caries prevention efforts. To obtain reliable information, it is necessary to draw a statistically complex probability sample and use trained and highly standardized clinical examiners and data recorders. It is necessary to contract for the conduct of this survey as it vastly exceeds our staff resources. We expect the survey to cost about $1.5 million. We are working very closely with the National Center for Health Statistics on this project. They have provided a generous amount of staff assistance in the design of the survey and the review of contract proposals. We intend to consult regularly with NCHS staff as this survey proceeds.

SUGAR SUBSTITUTES

Question: A recent article in the August 14 "Business Week" magazine stated that soft drink and cereal companies are dramatically increasing demand for new high fructose corn syrups as a substitute for sugar in their products. The article went on to say, because it has the advantage of tasting up to 50 percent sweeter than sugar, less can be used for the same degree of sweetness. It is now being touted as the only safe, low calorie sugar substitute. How does this substance compare with sucrose and/or saccharin in terms of its cancer effect? What cooperative programs do you have with the Cancer Institute in this area? Is the Dental Institute involved in studying the impact of such a dramatic transition to fructose on the nation's dental health?

Answer: So far as we are aware, there have been no suggestions that high fructose corn syrup is toxic in any way. Fructose is a normal metabolic product of sucrose and thus has been a common item in the diet for hundreds of years. We do not currently have cooperative programs with the Cancer Institute in this area. Our experiments have shown that fructose is only slightly less cariogenic than sucrose and is, therefore, not a suitable sucrose substitute from the standpoint of prevention of dental caries. Our efforts are directed toward the identification of safe, non-sugar sweetening agents which will not cause caries.

NATIONAL CARIES PROGRAM

Question: In 1971, the National Caries Program was initiated. In your opinion, what major advances have we made since 1971 in reducing tooth decay in the United States?

Answer: We believe that the National Caries Program has made substantial progress toward the goal of eliminating caries as a leading public health problem. The most conspicuous example is our recent demonstration of the cost-effectiveness of self-applied fluorides, both tablets and mouthrinsing, in schools. This preventive regimen is being widely implemented at this time. We have also greatly increased our basic knowledge of the interaction

of specific bacteria and dietary carbohydrates in caries causation. Steady and encouraging progress has been made toward development of an anti-caries vaccine, as well as slow release techniques for intra-oral delivery of fluorides and antibacterial agents. Our research has produced two other highly effective preventive techniques, adhesive sealants and fluoride gels, which have gained wide acceptance by dental practitioners. Recently we have identified and are testing an array of new non-cariogenic sweetening agents which have potential as sugar substitutes for use in snack foods.

COLLABORATIVE STUDIES

Question: Are you aware of a recent publication, "The Relative Efficiency of Methods of Caries Prevention and Dental Public Health", sponsored by the Public Health Service? In it, there are recommendations, pg. 258, regarding the need for collaborative studies in the U.S. on what seems to me to be dramatic results from tooth cleaning programs in Scandinavia. Could you please tell me about research being sponsored by the NIDR in this area.

Answer: Yes, we are aware of the recent publication "The Relative Efficiency of Methods of Caries Prevention and Dental Public Health". Members of the NIDR staff have contributed to this publication. We are very much aware of the interesting studies conducted in Scandinavia and have invited Dr. Lindhe to visit NIDR this spring to participate in considerations of additional research in this area.

ORAL HEALTH PROMOTION

Question: I understand the NIDR in the last year requested and received support to enlarge its program of oral health promotion. I believe this is to help dental health programs learn about and apply the results of dental research. As I see you propose to continue these efforts in the next fiscal year budget, could you tell me how you intend to use the findings from Scandinavia and other countries outside the U.S. in your technical assistance program?

Answer: Our activities in oral health promotion include the dissemination of a variety of informational materials, and limited staff assistance through speeches and seminars, to communities wishing to implement dental disease prevention activities. In general, we recommend those proven preventive methods with the most favorable cost-benefit ratios. The findings from foreign studies frequently contribute to these preventive measures.

DELIVERY SYSTEM

Question: What progress has been made in laboratory studies on a new delivery system for the slow release of fluoride compounds for preventive dental care?

Answer: Research on a slow release device for delivery of fluorides and other caries preventive agents has proceeded past the

laboratory phase. Studies in dogs have established that fluoride is released from the device at a predetermined rate for periods up to six months. We have now filed an Investigative New Drug (IND) application with the Food and Drug Administration for approval of clinical testing, and we expect to begin Phase I clinical trials this year. We have also developed a slow-release fluoride tablet which is designed to provide both topical and systemic exposure to fluoride. This is expected to be useful in young children in non-fluoride areas. Clinical trials of these tablets are in the planning stage.

FLUORIDATION

Question: Give us some specific examples of how you are helping the Center for Disease Control to publicize the importance and safety of water fluoridation programs and what effect it has in combating cavities?

Answer: NIDR provides liaison with Washington-based Federal agencies in obtaining or developing information needed by CDC to support their promotion of fluoridation, and we include fluoridation information in our responses to inquiries about dental health. For example, we have maintained continuing contacts with personnel of the NCI to assist CDC in effecting the urgently needed resolution of the fluoride-cancer controversy. We have initiated and supported by funding and staff assignments studies intended to resolve questions raised about fluoride intake and chromosome changes. In addition, we are moving to initiate research projects designed to meet specific information needs concerning fluorides and health, including several suggested by CDC staff.

Four NIDR pamphlets which describe better dental health for children and a guide to implementing school-based fluoride programs include a statement that fluoridation of public water supplies is the best method for the reduction of tooth decay. More than 200,000 pamphlets have been distributed and 15,000 guides have been sent out in response to specific requests.

NIDR includes in responses to inquiries about dental health the latest promotional pamphlet on fluoridation supplied by CDC when it seems appropriate to do so. For specific inquiries about fluoridation, we maintain a supply of more detailed information and promotional items. When inquiries for information are received that indicate an interest in community action, we specifically direct persons to contact CDC for more information and consultation. We have cooperated with the CDC in obtaining expert witnesses and information for hearings and legal proceedings.

PAIN CONTROL

Question: NIH just held a National Conference on Pain Control. This area is receiving more and more attention, Dr. Scott. What is your Institute doing in the area of pain control methods and behavioral factors involved in dental problems and disease?

Answer: The NIDR was among the first Institutes at NIH to emphasize pain research. It has taken a leadership role in support of major international symposia on pain and currently supports

research grants and intramural studies on various aspects of pain and its management. These include studies of basic neurophysiological mechanisms underlying oral sensation and pain, dental analgesia, temporomandibular joint pain, and pain measurement and perception. We are particularly encouraging efforts to expand findings from basic research to clinical settings.

The Institute recognizes that behavioral factors have a major impact on oral health. Community acceptance of water fluoridation and individual adoption of adequate hygiene practices are examples of how behavior and oral health are integrally related. Current research supported in the behavioral and social sciences includes studies on factors associated with children's acceptance of caries-preventive regimens, factors influencing self-care in the elderly, the prevention or reduction of excessive fear of dental treatment, and specific behavioral responses such as tooth-grinding which can impose unneccessary structural damage.

DENTAL AND OROFACIAL PAIN

Question: For several years, NIDR has supported research on dental and orofacial pain. I am informed that you have not funded some program projects that have received good priority scores to be funded. Why?

Answer: The NIDR currently has one approved but unfunded program project concerning orofacial pain. This program project has not been funded as yet because to do so would preclude timely funding of a number of individual project grants, with comparable or better priority scores in the pain control area. As the fiscal year progresses we will continue to reexamine our funding capabilities.

PRIORITIES

Question: Dr. Scott, which of your resesarch programs do you think are your highest priority?

Answer: Over the years we have refined our program so as to comprise the six most important areas of investigation in our field. All are of high priority, but were we to select the highest, we would be inclined to identify research on caries and periodontal diseases, because of the essentially universal prevalence and high economic burden of these diseases.

250 PAY LINE

Senator SCHWEIKER. All right. Now, next, I would like to turn to you, Dr. Fredrickson.

I had some questions this morning that I delayed because they were longer than my time or allocation was permitted.

I would like to direct them to you now. They basically have to do with the idea of having a 250 pay line for NIH Institutes.

I guess I'll start out with a couple of fundamental questions. How much will it cost the Congress and taxpayers this year if in fiscal 1980 we were to continue to pay all programs and Institutes at NIH at the 250 pay line level?

Dr. FREDRICKSON. Based on our estimate at the present, it would take about $400 million in addition to this budget request.

Senator SCHWEIKER. One of the problems I see with the 250 pay line is that obviously it increases in cost each year, and to some extent this makes it an increasingly difficult problem to target, and identify the priority areas in your research.

The President proposed a standpat budget, and the chairman is talking about a 5-percent cut.

So that presents a problem.

Second, councils may get in the habit of approving more applications at a 250 approval rate level as normal if that becomes known as the break-even point in terms of go or no go for a project. And finally by approving all Institutes at the 250 pay level, aren't we in essence saying that every pay level at NIH has a highest priority?

I guess what I'm leading up to is to ask, isn't there a better mechanism, some kind of objective mechanism, which the NIH ought to be thinking about developing than the 0 to 500 pay line?

Dr. FREDRICKSON. Senator Schweiker, that is a question that we often think about. There is nothing magic about the 250 pay line. It does insure scientific merit which is a major concern. I think that the actions of the study sections in reviewing the applications and assigning those pay lines performs a service that all of us depend upon to assure the quality of the biomedical research the public buys with its money.

There is no doubt that program relevance is also important. One must not look strictly at the numbers. Program decisions have to be made, and in times of austerity, these decisions are even more difficult because selections must be made upon high priority programs.

I think that there are several possible substitutes for a pay line that is based on priority score alone, and I would like to suggest two of them. One method that would be desirable would be to fund a constant number of new grants each year.

Using this method, I do not believe the excellent quality of research would be sacrificed. Given the market and the exercise of the peer review system, the quality of research should not decline.

Another system would be to attempt to maintain an award rate within some narrow range. It says that you would like to buy excellent grants, and you would like to buy as many of them as you can.

Senator SCHWEIKER. One of the problems is that research begets research. That may be a blessing or a problem. Obviously, the more

you expand in the field, the more interested scientists are drawn in, and the more projects become viable. I use that not solely as a criteria. It discriminates against a lesser known field, but the lesser known field may be just as potentially challenging or potentially helpful to the health of our people as a system that is operating full tilt, so to speak.

I know we sat in conference with the House, I guess it was a year or so ago, and they used the 250 pay line as a criteria for funding. I have some fundamental trouble with that.

FUNDING COMPETING GRANTS

To pursue it another way, maybe I should approach it on this side of it: How many competing research grants were funded by the fiscal 1979 appropriations?

Dr. FREDRICKSON. The number of grants that we expect to fund in fiscal year 1979 would be approximately 15,200. That would include noncompeting continuations, and new and competing renewals that we would expect to fund this year, Senator Schweiker.

Perhaps a comparable figure for this budget for 1980 would be 14,484. We expect the number of grants to drop by about 700.

Senator SCHWEIKER. You are including competing entities?

Dr. FREDRICKSON. Yes; I am.

Senator SCHWEIKER. You expect to drop how many again?

Dr. FREDRICKSON. About 700 grants in total, including competing grants, with this budget.

Senator SCHWEIKER. 700 out of 15,000?

Dr. FREDRICKSON. That is the net decrease.

Senator SCHWEIKER. That is 5 percent.

Dr. FREDRICKSON. That is right.

Senator SCHWEIKER. What I'm getting to is, I wonder if we shouldn't be looking at some other kind of way of evaluating some of our work and giving it priority. Maybe to make some areas more fair.

In other words, it seems to me that research that has a basic relationship to life support, life maintenance, ought to have some kind of high priority than some of the other things we do.

Dr. FREDRICKSON. We certainly do consider high priority areas, and attempt to give them emphasis within budget limitations.

Senator SCHWEIKER. A person who can't see or can't walk and hear that had a fundamental incapacity ought—there ought to be some mechanism here for funding that is put into the peer review system. I think another followup on it is cost effectiveness, the very thing we are looking at in the Heart and Lung Institute. You can show a very specific return for what we are investing in terms of savings, for health costs, or people's lives.

PRIORITY SCORES

I just wonder if we ought to be looking at some evaluation system that relates to principles like these, rather than the 0 to 500 system. I think the system itself begets irregular comparison and sort of feeds on itself in terms of being successful, one gets more successful, and more people know there is money in it, more

people invest their time and effort in it, because the people know there is more money in it.

Dr. FREDRICKSON. I believe, Senator Schweiker, that the 0 to 500 system is used primarily to judge the quality of a scientific proposal. Is it a good idea? Will it work?

That is the first judgment, but not the last one. The program judgments that you allude to are also important, and they are made by the individual Institute's programmatic orientation and by its council. Therefore, we do have judgments, both qualitative and programmatic. We have a limit as to how many we can fund, and this year we are seeing an enormous limitation on the number that can be funded. We will be paying only to around 170 in some Institutes.

Senator SCHWEIKER. I know you will, Dr. Fredrickson, but I don't think that tells me one thing about what we ought to be doing. That is what disturbs me about the system.

Dr. FREDRICKSON. Senator Schweiker, I think that it does give you and me a fairly good idea of how much there is out there in the market in the way of good ideas to be explored. It tells us that there is excellent science out there that we can buy, and we know we can't buy it all. We shouldn't expect to buy every idea that is considered good. But there are many, many approved excellent ideas that we can't buy. We expect that also. That number game does tell us about the quality of the research which is available. Then the selections that we make are determined by these program relevance factors, with each Institute setting aside a certain amount of money to buy these ideas at different priorities. The Institutes also use that money to fund the other ideas that you talk about, issues that relate to technology transfer, to applications, to developing clinical talent, and other opportunities.

I think what that number does, and it is a lot, is to tell us within the science base area of investigator-initiated research, that we have a certain quality of application. The number or percentage of approved grants that we can buy tells you the number of ideas. Basically, what it tells you is how many scientists you can support with the system. In my view, if you know you have more research ideas out there than you can buy, you have to make some decision as to how big a biomedical research system you want in the country. I think that is the key question. In a way, you make that determination by deciding how many of these research grants we can support.

Senator SCHWEIKER. Maybe the system benefits you more than it does us. I won't argue that. You may well have very fixed parameters as to what you see about it. But I think it certainly doesn't help our dilemma, when a group comes down to Congress and says, hey, you are neglecting us. Sure, we hear this all the time, and you get into the disease of the month category.

The point that I am making is, instead of getting a political judgment in the system, shouldn't we have a more objective judgment from you, the scientific community, as to what life support system is really being penalized because we haven't done research in a year? Sure, maybe there aren't proposals, and sure, maybe there aren't trained investigators. Instead of just looking as to whether there are proposals or trained investigators, isn't part of

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our job to give the whole system some oversight and see whether we are deficient here, and not wait until somebody comes down and hits us over the head politically, and says, hey, everybody is neglecting diabetics, or multiple sclerosis victims.

ROLE OF ADVISORY COUNCILS

It just seems to me if we had an evaluation system related to life sustenance, life support, incapacities of people, and the cost return to the country of savings by health prevention, or the ability to get people who are not functioning assimilated in the system, we would have a little more objective way to go back to the groups that come to us, and say, now, we are doing what we can do through a system of priorities. The pay line may help you earmark the intelligence of an idea, but I'm not sure that we take it the next two steps, which is how that idea relates to the benefit of the country in terms of medical payoff, how it relates to who we are not going to see incapacitated that would be incapacitated if we didn't invest in this area, and also what relevancy it is to the number of people involved.

Dr. FREDRICKSON. I understand precisely what you mean. I think we do that. That is exactly what the Council is supposed to do.

Senator SCHWEIKER. I'm not clear how that impacts on your system. It certainly doesn't come through to us.

Dr. FREDRICKSON. Let me try to make it clear for you. The Councils look at all these programs, in which we have all the grants with their priority scores, rated for their scientific quality. The Councils make judgments as to how much money an Institute should put into this or that program, making their judgments based on a broad, and I think basically very objective review. Five or six of our Institutes now publish extensive analyses and program plans. Shortly, we will be able to provide you a draft report of the Neurological Institute, which discusses the program in terms of the opportunities and the needs and what can be done. It gives you that long——

Senator SCHWEIKER. We didn't even have an Eye Institute until recently, and it was just because a Congressman introduced a bill in the House, that a friend of mine from Pennsylvania sort of blew the whistle on the system, and all of a sudden we had an Eye Institute.

We probably should have had an Eye Institute for some time. Eye disease is a very severe thing. I think the Eye Institute is doing great now, with the investment we have, and the laser technology, et cetera.

Why does it take a bill through the system to sort of blow the whistle at the Lions Club, you know, which really did get behind it and politically made it sound? Why does it take that kind of a system?

We are ringing bells from the outside in, rather than from the inside out.

Dr. FREDRICKSON. No. Research on the eye was being conducted in the Neurology Institute long before there was an Eye Institute. There was a division of that Institute which was moving forward,

and it was simply lifted out, given more illumination, size, and autonomy.

Senator SCHWEIKER. It was lifted out because the people who were blind didn't feel they were being judged properly, in terms of financial support, training, and all the other criteria we use.

Dr. FREDRICKSON. I think that is true about all the people who have an affliction.

Senator SCHWEIKER. Right. But we don't have a scientific, rational evaluation method of doing that. I think that is our job as scientists and politicians to have some system to determine who is getting shortchanged in this whole area, who are we missing, and who we aren't missing.

Dr. FREDRICKSON. We feel that is our responsibility; and I think we believe we can help you in making those decisions. That is why we are here, because we can give you objective analyses of what we think are the opportunities and the needs.

250 PAY LINE

Senator SCHWEIKER. The 250 pay line perpetuates the status quo?

Dr. FREDRICKSON. The 250 pay line is a highly objective analysis by the technical experts making general but very important determinations of excellence in any of these areas. We should be buying the most excellence signs that we can for our money.

They say here is an idea; it relates to the other idea, it is a good idea, and it will work. And they rate them against each other as best they can. If it receives a score of 100, it is a better idea than a 400 score. If you want to put so much in the high priority research, as the Nation does, then you want to be buying "100 stuff" as often as you can, rather than 400, because it is not as good an investment.

That is why we have a system for rating these grants. I think it is an excellent system; but it is not enough by itself. There are many more important considerations in determining total allocations. How much do you want to put into those grants; how much do we advise you to do; how much new clinical applications, trials?

I think this is our job, to know that whole continuum of research and to try to give you the most for your money. I think we do it.

ROLE OF ADVISORY COUNCILS

Senator SCHWEIKER. Is there a specific rating system for any of these points that I mentioned in the 0 to 500 scale?

Dr. FREDRICKSON. Yes, there is. We put many of these decisions aside in regard to the first review, because we say the value and program judgments belong in the second one, the Council reviews.

We can't fund one grant without the approval of a Council. That's what the law says, and I think that is an excellent idea. The two-tiered review system is a superb way for scientific merit review and for making program decisions to purchase information or research for knowledge. I think it works.

Dr. WHEDON. May I indicate, Senator, what Councils do, they tell us not to pay to the same priority score in every part of our program. In fact, along through our Institute, our 10 different

programs have paid to different priority levels. The institute Council has recommended that we make these choices.

So the second part of the system does work in making selections in dealing with perceived needs and opportunities and urgencies.

In other words, the priority score is only the first decision. It is a decision as to excellence, but then the final choice as to what gets paid is a selection process made by a combination of staff and the National Advisory Council. And we think it works because we see that among our different programs we pay to different priority scores.

Dr. FREDRICKSON. The priority score, Senator Schweiker, is like a consumer's rating. It tells us which is a better toaster. How many toasters we want to buy is a decision that is made in a different way.

DIABETES FUNDING

Dr. WHEDON. Let me give a specific example: The diabetes program in our Institute paid further along the line than any other program.

Senator SCHWEIKER. I'm a diabetic supporter; but I'm not sure that is good or bad. I'm sure the people who I have worked with will feel that is very good.

My question is: Do I know whether that is good or bad? That is my fundamental question. Is that good or bad?

I'm sure the diabetic community feels that is very good. I applaud that. My question is: In my oversight job and your job, is that good or bad?

Dr. FREDRICKSON. If we are paying for low priority projects in diabetes, we will let you know. We will give you our opinion.

Senator SCHWEIKER. I agree with your illustration, but the question is whether that tells us what we really need to know.

I support this, I'm an advocate, obviously, but we have obviously tripled diabetes funding here in the Senate and the House, and that to some extent is the reason that we have the pay line where it is.

I'm sure that the ratings you give it under the system show that there are good, new investigators coming in with good, new ideas.

But the point is we had to prime the pump there, as in the Eye Institute and others, to get that rolling; and should it happen from the grassroots up instead of from the top down?

SYSTEM FOR ALLOCATION

Part of the trouble is, I think, the committees that have oversight in this area either don't fully see the system in your eyes, or aren't apprised of how the subjective part of the process works.

Have we ever used any other system, and do any other countries use any other system? There are obviously other systems in other countries.

Dr. FREDRICKSON. There are other systems. In fact, all systems must revolve around some evaluation by the technical experts as to whether, first of all, it is a good experimental proposal.

One can argue at length about this. But nearly all allocations of research money for science are made on the basis of technical judgment, workability, and research opportunity. There must also

be a relative determination of need in making the selection of which projects to fund, because there is always more than you can fund.

Senator SCHWEIKER. Doctor, let me ask you this—I don't want to prolong it. This is one of those things that you could discuss for some length of time, obviously.

In your judgment, excluding our own country, who are the top two or three countries in the world that have what you consider good peer review, or good scientific review systems? What countries come to your mind, excluding our own now, that have a mechanism that you would feel is good?

Dr. FREDRICKSON. Most of the countries in Western Europe have adopted the American system because they learned it from us. The West Germans use the same kind of peer rating system. The Medical Research Council of Britain, and of Canada, for that matter, again use a very similar system.

This is true for Scandinavia, and for practically all of Western Europe.

In fact, it is said to be the same in the socialist countries behind the Iron Curtain. The Russians use the Ministry of Health and the Academies to make the same judgments. Basically, the first judgments are those of the scientists, and then social and political judgments are applied secondarily.

But in all cases, the scientists have to make the decision about the quality of the idea.

Senator SCHWEIKER. Maybe there is a linkage between what you are doing and what we are doing that needs to be made, as opposed to the system that we are using. We need a way of making gross decisions.

I mean, here we are, the President sends us a standstill budget. Standstill budget means zero growth for all the Institutes The chairman is talking about a 5-percent cut on top of the 8- or 9-percent inflation factor that isn't accounted for by the budget.

We have no way under the system we are using of making judgments. I think you, yourself, will acknowledge that is not the best way to make a cut, or determining spending, from our point of view.

Dr. FREDRICKSON. It is only the beginning. It is one way.

BUDGET REDUCTION

Senator SCHWEIKER. What linkage can you supply us with to give us a little more benefit out of the system that you feel is working to guide us in these gross decisions?

Dr. FREDRICKSON. We are quite prepared, Senator Schweiker, in every area represented by these Institutes and divisions, to tell you what we can or cannot buy, where we have to make the cuts, and what they would mean in terms of programmatic change.

When you asked the 5-percent question——

Senator SCHWEIKER. That was Senator Magnuson's 5 percent.

Dr. FREDRICKSON. Excuse me.

Senator SCHWEIKER. I'll take the blame for any cuts I propose.

Dr. FREDRICKSON. We can give you a clear-cut and objective evaluation, as to what you can or cannot buy at different funding levels of any part of the budget.

Senator SCHWEIKER. That is a good point. He's asking you to say something about priorities in connection with a 5-percent cut because we don't have any other criteria to use.

That 5-percent cut approach is a very popular thing around here.

I think that is really a cut with a meat ax; you know, 5 percent across the board. That is just what we are coming to because we don't have a selective way of viewing this thing.

That is exactly my frustration here. We ought to be exercising some judgment, some oversight, as to where the life support functions are, where we can help the most people, and who has been neglected, and who hasn't.

And all we do is say, "make a 5-percent cut," because that is all we seem to know how to do.

The system that you are using gives us no alternative but to talk 5-percent cut. And I don't think that is a good way to run a research department, and I don't think you think it is, either.

Dr. FREDRICKSON. No, I don't think it is.

ROLE OF PROGRAM DIRECTORS

Senator SCHWEIKER. That is exactly right. But that is the point that we are left with, because we have no other tools, no other mechanism, no other index to make judgments; the 250 pay line notwithstanding.

Dr. FREDRICKSON. The Senate and the Congress in their wisdom when they set up the NIH established all these various Institutes and divisions. Each of the Directors is prepared, because that is their job, to determine what are the needs, or the opportunities within each of their relevant areas. They can do that.

We are prepared to provide you any information, because that is our job, to assist you in making these decisions. And I think we can do that, Senator. We know what the programs are all about. That is what we are supposed to be doing every day. We can tell you where to put a 5-percent increase or decrease.

Senator SCHWEIKER. Obviously we are going to have to do that, if we accept the question that is being proposed.

Well, I think I've pursued it far enough. I think it is a very basic and fundamental question, a question I think you all ought to ask yourself.

I think it is probably performing well from what you perceive the system to be, but I don't think it is performing well for what we see is the need of the system, or we wouldn't have to be falling back to 5-percent cuts.

That is what I am upset about. I don't think we have any recourse but to talk about that, because we have no other objective way of looking at it in terms of where we ought to be prioritizing our research.

Dr. FREDRICKSON. We are buying exploration into the unknown, and we can't promise discovery on a particular schedule. What you must know at the minimum is that you have honest people doing the best job that can be done.

If you want to look to something, we must provide you the best mechanism available to do that. You can't look for everything.

Senator SCHWEIKER. If you provide us a good mechanism, and we give you a 5-percent meat-ax approach, I'm not sure the system is working well.

Dr. FREDRICKSON. No, because then we would only have 95 percent.

Senator SCHWEIKER. Right.

AWARD OF COMPETING GRANTS

One figure that you should put in the record, in terms of the budget: You gave me, Dr. Fredrickson, a total of the grants, both competing and noncompeting. I want to ask you the same question for fiscal 1979 versus fiscal 1980 in terms of competing grants that will be awarded under the 1979 budget and the proposed 1980 budget.

Dr. FREDRICKSON. Senator, we expect to award about 5,670 competing grants in 1979, and under this present budget in 1980, we would award about 3,062 competing grants.

Senator SCHWEIKER. So that is about a 30-percent cut in new grants?

Dr. FREDRICKSON. I believe the reduction in competing grants may be somewhat larger than that.

Senator SCHWEIKER. So we are cutting out about 30 percent.

You gave us a figure to get down to the 250 pay line, as I recall. Would it take something like $400 million?

Dr. FREDRICKSON. That is correct.

Senator SCHWEIKER. Is there any rough relationship between that figure and these figures, or not? In other words, if we got the $400 million, would that put us back to the 5,670 level or not?

Dr. FREDRICKSON. A little bit more, probably; because we are not paying to 250 in 1979. We estimate the pay line in 1979 to be around 240 or 235.

STABILITY OF RESEARCH

Senator SCHWEIKER. What does all this mean in terms of stability of research, in terms of what your budget is, and what the 1979 figures are?

Dr. FREDRICKSON. Looking at the system affected by research grants, the scientists out there, we can give you kind of a rough figure, Senator Schweiker.

We lose about 2.6 full-time equivalents per grant, so this means that roughly 2,000 fewer people will be doing research.

We will be shrinking the system.

Senator SCHWEIKER. By 30 percent?

Dr. FREDRICKSON. No.

Senator SCHWEIKER. With new entries?

Dr. FREDRICKSON. If we compare 1979 with 1980, because since we have more continuations in 1980 than we had in 1979, our total grants are not shrinking by 30 percent. We are shrinking by about 5 or 6 percent.

Senator SCHWEIKER. All right. We spent plenty of time on that. But it is a pretty fundamental question, and I think we ought to stand back and look at our system or evaluation once in a while.

National Institute of Arthritis, Metabolism, and Digestive Disease

STATEMENT OF G. DONALD WHEDON, DIRECTOR

1979 APPROPRIATIONS AND 1980 BUDGET REQUEST

Senator Schweiker. Now we are going to hear from the National Institute of Arthritis, Metabolism, and Digestive Disease.

Dr. Don Whedon is the director. Your budget request for fiscal year 1980 is $305,746,000. This is an increase of approximately $3 million over the level provided in fiscal year 1979.

PREPARED STATEMENT

Dr. Whedon, let's put your whole statement in the record, but I will give you the prerogative of summarizing anything you would like to do.

[The statement follows:]

STATEMENT OF G. DONALD WHEDON

Mr. Chairman and Members of the Committee:

I am grateful for this opportunity to report on the progress of the research programs of the National Institute of Arthritis, Metabolism, and Digestive Diseases (NIAMDD) and to testify to the needs of these programs for fiscal year 1980. The wide range of our categorical disease responsibilities includes arthritis and rheumatic diseases, diseases of the bone and skin, diabetes and other endocrine and metabolic disorders, digestive diseases and nutrition, diseases of the kidney and urinary tract, and diseases of the blood.

The National Commission on Digestive Diseases which recently reported to the congress in January and earlier reports of the respective national commissions on diabetes and arthritis gave ample testimony of the magnitude and severity of health problems presented by these chronic diseases. We are well aware that only new knowledge can relieve their toll of disability, suffering, and death.

I wish to describe the ways in which we are meeting the challenge of our responsibilities, and to sketch the background of salient Institute programs.

Arthritis and Related Musculoskeletal Diseases

Arthritis and rheumatic diseases are very common, painful, crippling diseases, afflicting over 30 million people.

Research on rheumatoid arthritis, a major crippler, has produced important new information on the mechanism of joint damage. Immune complex proteins containing rheumatoid factor cause the release of (lysozomal) enzymes which then attack cartilage. Cells of the rheumatoid joint lining produce another enzyme, collagenase, which destroys the collagen of cartilage. Antibodies to the type of collagen found in cartilage have recently been discovered in the blood of patients with rheumatoid arthritis. An effective new drug, D-pencillamine, thoroughly tested with NIAMDD support, is now available for treating rheumatoid patients. In the past few years, increasing evidence has accumulated from serological and chemical studies of large populations that predisposition or susceptibility to certain diseases may be inherited characteristics. We have reported to this Committee such evidence as it has emerged with respect to one rheumatic disease, ankylosing spondylitis. In systemic lupus erythematosus, a serious disorder of young women, promising additional new leads include lack of certain factors normally produced by lymphoid cells and the possible protective effect of androgens (male hormones) in experimental animal modes.

I am pleased to report that our new Multipurpose Arthritis Centers as outlined in the Arthritis Plan are well underway. The prime purpose of these 24 Centers is to foster an optimal combination of arthritis research, training, professional and patient education, and community health projects. Our orthopedics program encompasses both fundamental and clinical studies of bone and cartilage in normal and disease states. One example of new research in the orthopedic field involves bone healing and regeneration in patients with unhealed fractures unresponsive to pinning, grafting, or fusion.

Diabetes and other Metabolic Diseases

In the past three years the Congress has provided the Institute with large increases in funds for activities related to diabetes. This increased emphasis has enabled us to intensify greatly our research efforts, including the relationship between genetic factors, immune mechanisms and infectious agents in the causation and development of diabetes and its complications. New accomplishments include the recent production of a synthetic insulin that is a biological carbon copy of human insulin. A forerunner of this work was the artificial creation, in bacteria, of a form of rat insulin by a team of NIH-supported scientists at Harvard University through the use of recombinant DNA techniques. Paralleling this and other research efforts and consistent with the plan proposed by the National Commission on Diabetes and supported by this Committee, we have now established eight Diabetes Research and Training Centers in order to increase the scope and tempo of Federally-supported research and training activities on this disorder.

Another metabolic disorder of deep concern to us is cystic fibrosis (CF), a serious hereditary disorder of children. One new research development is the observation that cultured cells from cystic fibrosis patient are more resistant than normal cells to the toxic effects of dexamethasone, a synthetic corticosteroid hormone. The phenomenon of relative resistance to dexamethasone may prove useful in the prenatal diagnosis of CF and even in identification of asymptomatic CF trait carriers.

Endocrine Disorders

Research in endocrinology, study of the endocrine glands and their hormonal secretions and their effects on the metabolism and physiology of man, is one of our important concerns. The major emphasis within the endocrinology program will continue to be on basic research and its application to the processes and dysfunction of growth, reproduction, and metabolism. Our clinical studies include investigations of such abnormalities as hypopituitary dwarfism, acromegaly, thyroid disorders, and adrenal gland dysfunction, among others.

Digestive Diseases and Nutrition

The report of the National Commission on Digestive Diseases which was just released, points out that digestive diseases account for 10% of the economic burden of illness, and for 15% of admissions to general hospitals and are the prime cause of major surgery. Peptic ulcer causes about 8000 deaths each year, many of these due to hemorrhage. Studies now underway suggest that it may be possible to treat cases of bleeding of an ulcer by cauterizing the bleeding vessel through an endoscope. There are over 300,000 operations for gallstones each year. We are learning about how obesity and certain female hormones affect the secretion into the bile of cholesterol which is a major component of gallstones. Cirrhosis of the liver causes the deaths of over 30,000 Americans a year and is in fact the sixth leading cause of death by disease. Many of these deaths are caused by hemorrhages contributed to by constriction of blood vessels by the scar tissue that forms in these disease livers. We are now learning about factors that influence the laying down of this scar tissue (collagen) and hope to be able ultimately to limit its formation or cause it to be restored.

Our nutrition program has joined other Institutes at the NIH in proposing to support Clinical Nutrition Research Centers. These Centers should serve as a focus in medical schools for nutritional research activities, bring new investigators into the field, increase teaching of nutrition and improve the nutritional care of the patients. Our

nutrition research encompasses a spectrum of activities from basic metabolic and physiologic studies to those directed toward correction of malnutrition, specific nutritional deficiency diseases, and obesity. In the latter area, we have sponsored a "consensus development conference" on intestinal bypass surgery, an often controversial treatment for massive obesity, and related new surgical treatments. We expect to amass much-needed additional outcome data concerning these procedures and other approaches.

Urologic and Kidney Diseases

Almost thirteen million Americans are afflicted with acute or chronic disorders of the kidneys and urinary tract. Our research program in kidney disease and disorders of the urinary tract is searching for new methods of preventive therapy, earlier diagnosis, and more effective treatment through expanded knowledge and understanding of the basic mechanisms and causes of the various disorders. This program encompasses basic studies of the strucure and function of the kidney and urinary tract, research on diseases caused by aberrant immune processes which result in the various types of glomerulnephritis, and studies on disorders such as urolithiasis (kidney stones) benign prostatic hyperplasia, polycystic kidney disease, and congenital malformations. Further, we are seeking fundamental understanding of and ways to improve kidney transplantation so that this mode of treatment can be a more efficacious therapy for end-stage renal failure. At the same time we are seeking better understanding of the complications of chronic renal failure so that appropriate treatment and prevention may be devised for them. We continue to emphasize studies to reduce the cost and to increase the clinical effectiveness of dialysis. An alternative to hemodialysis, peritoneal dialysis, utilizes the lining of the abdominal cavity (the peritoneum) as the membrane through which uremic waste products are filtered and ultimately removed from the body. A promising improvement in this technique is the continuous ambulatory peritoneal dialysis system (CAPD) currently under investigation by Institute-sponsored researchers.

Hematology

Research on blood is an integral part of the Institute's program. One of our research goals is enhanced basic understanding of the physiology and metabolism of blood and its components. Such knowledge is essential for a better understanding of the many normal functions of the blood as well as its various disorders, including the nutritional anemias, anemias of chronic diseases, and altered structure and function of hemoglobin, the mechanisms which cause them, and ultimately, for improved diagnosis and therapy in this field.

Dermatologic Disorders

As you know, our Institute is responsible for research on disorders of the skin, such as the disfiguring and incapacitating disease, psoriasis. Other serious, disabling, and disfiguring skin diseases currently subject to Institute-supported research include vitiligo, atopic dermatitis, and pemphigus. In vitiligo, we have organized a new sizeable consortium grant involving a number of knowledgeable investigators who will engage in a coordinated study.

In conclusion, Mr. Chairman, the budget request for the Institute for 1980 is $305,746,000. I shall be happy to try to answer any questions the Committee may have.

Dr. WHEDON. Thank you, Senator Schweiker. I would like to give you a brief summary indicating our plans for 1979 and 1980.

First, let me say the committee is quite familiar with a very wide range of our research responsibilities organized in 10 program areas by discipline or groups of diseases, and I am submitting special reports describing detailed progress in the most important of these areas.

But to go on and give a brief skimming summary across our whole set of programs: In arthritis, new information is emerging concerning the mechanism of joint damage in rheumatoid arthritis through a series of reactions initiated by unknown factors, such as a possible virus, and involving protein components of blood and joint tissues, tissue digestive enzymes, are released which attack, inflame, and eventually destroy cartilage lining of the joints.

A relatively new drug, D-penicillamine, is demonstrating effectiveness in counteracting these events. Studies are now engaged in determining the best dose which yields maximal results while keeping serious side effects to a minimum. The number of new multipurpose arthritis centers has been increased to 24.

Simultaneously, we are increasing our efforts in osteoporosis and on the factors which underlie the abnormal changes in bone cartilage in the so-called "brittle bone" disease, osteogenesis imperfecta. Also in the orthopedic field, we can report developing success with new methods, particularly electromagnetic field stimulation, which facilitate the healing of recalcitrant fractures and congenital false joints which are resistant to conventional attempts by pinning, grafting, or fusion.

In the field of skin diseases, research is continuing against psoriasis, and a new, sizable consortium grant has been awarded to initiate a coordinated study on vitiligo.

A major increase in funds has expanded very significantly our research activities in diabetes, where new accomplishments include the production of a synthetic insulin that is a biological carbon copy of human insulin. In this area, we have now established eight diabetes research and training centers to increase the scope of the fight against diabetes.

The research effort against another metabolic disease of deep concern to us, cystic fibrosis, is also being given more emphasis, and research related to the various endocrine glands and hormones which influence so many body functions is continuing.

The National Commission on Digestive Diseases has recently reported to the Congress voluminous testimony concerning the magnitude and severity of health problems presented by those diseases. Developments in this field include new techniques of direct intervention with the aid of endoscopes in bleeding ulcers, and continuing cooperative study of nonsurgical—medical—treatment and possible prevention of gallstones.

In nutrition, we have initiated, along with two other institutes, a series of new clinical nutrition research center programs, mentioned by Dr. Fredrickson this morning.

In kidney diseases, search for new knowledge with which to prevent or cure kidney disease is being pushed in order to diminish the large number of individuals who face fatal irreversible kidney

failure each year, and who then must be treated with costly artificial kidney dialysis, or transplantation.

Finally, we are also responsible for supportive research in hematology, particularly with respect to red cell function and synthesis of haemoglobin.

DIABETES

Senator SCHWEIKER. Dr. Whedon, we just had hearings about this, so I won't press you too much today. Except to say I think that in regard to some of the breakthroughs in the diabetes area, particularly, you can also show a good cost effectiveness, and cost relationship, like the Heart, Lung, and Blood Institute, in terms of benefits to groups involved, and I think that is a good case in point as to what the impact is on people who otherwise would have a very high layout of money for health problems.

So I think that is the point.

Some of these we have really asked before, Dr. Whedon.

What progress has been made toward diabetes research and to better serve the public's need in this area since last year?

Dr. WHEDON. Well, besides the fundamental approach, which, of course, is to support the basic research project, the grants, I think the most visible increase is in the number of diabetes research and training centers, which have now reached eight in number. This program was started in 1976 and 1977, and the purposes of these programs are not only to provide a locus for improved coordination of research, but also the basis for better training, for education of patients and the public, as well as professional postgraduate education, and also for experimentation in the area of community projects in order to find ways of improving and conveying better care to diabetic patients.

OUTLOOK FOR THE FUTURE

Senator SCHWEIKER. Why don't I just ask you to supply a more complete report on the record in this area, and what your expectations are in the coming years?

Dr. WHEDON. I will be happy to do that, Senator.

Senator SCHWEIKER. Let's do it two ways. Let's first do it for diabetes in all the Institutes. Your Institute is the lead Institute. So let's do it for diabetes for all Institutes.

Then I would also like it broken down by the other categories, such as arthritis and so forth.

Dr. WHEDON. All right.

[The information follows:]

NIH DIABETES PROGRAMS

National Institute of Arthritis, Metabolism, and Digestive Diseases

The National Institute of Arthritis, Metabolism, and Digestive Diseases (NIAMDD), the lead NIH Institute for diabetes research, will continue its traditional support of research in diabetes and related endocrine and metabolic disorders as well as newly initiated diabetes-related programs recommended by the National Diabetes Commission and the National Diabetes Advisory Board. Efforts will continue to elucidate the secretion and mechanism(s) of action of insulin, glucagon, somatostatin and other hormones as they relate to diabetes. Studies of insulin secretion and action relating to diabetes, as well as the interrelationship of diabetes with other metabolic processes and nutrition, will be encouraged. The extensive long-term studies on the Pima Indians by the Institute's Southwestern Field Studies Section will be utilized to expand our understanding of the epidemiology and genetics of diabetes and of the development of the complications of this disease. In a continued effort to achieve better control of diabetic state, research will be increased on islet cell and pancreatic transplantation and the development of artificial devices for controlling blood glucose levels. A program of multipurpose Diabetes Research and Training Centers (DRTC) initiated in Fiscal Year 1977 and devoted to achieving an optimal mix of research, training, education and translational activities, will continue. The Institute would like to expand its support of research into the role of genetic factors and of viruses in the etiology of diabetes, and studies of the relationship between diabetes, diet, and obesity are planned. Studies to assess the effects of control of blood glucose concentration on the development of the chronic complications of diabetes including investigations in animals and clinical trials are planned. New initiatives in epidemiological research and on the behavioral and psychosocial aspects of diabetes are anticipated.

The Institute would like to expand its Diabetes-Endocrinology Research Centers program beyond the present three Centers. In addition, expansion of the Multipurpose Diabetes Research and Training Centers program is planned to provide a broader, more balanced attack on diabetes. A National Diabetes Information and Education Clearinghouse will serve as a means of addressing the need for a central resource for educational materials and information, and a National Diabetes Data Group will foster collection, analysis and dissemination of diabetes data.

The Diabetes Program intends to give strong attention to expanding training for research manpower. In particular, expansion of the NIAMDD's Clinical Investigator Award program and of the newly developed Special Emphasis Research Career Awards in Diabetes (a collaborative effort between the National Institute of Arthritis, Metabolism, and Digestive Diseases, National Heart, Lung and Blood Institute and the National Institute of Child Health and Human Development) and New Investigator Awards in Diabetes is planned. Increases in fellowship support in diabetes are planned and increased research training through the multi-purpose centers programs will be encouraged.

National Eye Institute

Diabetes is a leading cause of new blindness and visual impairment in the United States today. The National Eye Institute (NEI) plans to intensify its efforts to understand better the causes of, and to prevent, cure or better treat this complication through support of: (1) the Diabetic Retinopathy Study to establish a scientific basis for the use of photocoagulation in the treatment of proliferative diabetic retinopathy; (2) a new multicenter clinical trial -- Early Treatment Diabetic Retinopathy Study -- to determine the best timing during the course of the disease to administer photocoagulation or other therapies; (3) the continued development of plans for eventual clinical evaluation of chemical substances that inhibit the enzyme aldose reductase and thus have potential value in treating complications of diabetes in the lens, peripheral nerve, and retinal vasculature; (4) the initiation of clinical trials of therapies for other retinalvascular disorders; and (5) fundamental and clinical research studies utilizing vitreous fluorophotometry to examine the normal and pathological properties of the blood-retina barrier and to improve capability for early diagnosis of retinopathy.

Major attention will be given to expanding the fundamental knowledge base through the stimulation of new investigator-initiated research projects and the training of laboratory scientists and clinical investigators. Of greatest interest will be new investigations on (1) physiological factors influencing blood flow, edema formation, and capillary closure; (2) angiogenic substances, antagonists, and inhibitors; and (3) transport processes between the retina and its blood vessels.

National Institute on Aging

Diabetes is a prime example of the complex interaction of aging process and disease states. The National Institute on Aging (NIA) plans to increase its support of research on the causes of the well recognized but poorly understood decline in glucose metabolism with age. Its ongoing prospective multidisciplinary study of normal aging in over 1,000 male volunteers aged 20 to 29 years, in which several diagnostic tests for diabetes are administered, will be continued. The results of this prospective, longitudinal study permit examination of factors which may be of great importance both in aging and in diabetes; e.g., obesity, nutritional factors, activity levels, medications, serum lipids.

In addition to this large scale epidemiological study, efforts to elucidate the underlying mechanism of the decline in glucose tolerance with age will be conducted. Some areas judged in need of more research activity include examination of the influence of age on the biosynthesis and processing of insulin, and the development of suitable techniques for the culture of beta cells.

The behavioral and psychosocial problems of the elderly diabetic are of special concern because of the sometimes severe loss of control of physical and mental functions. Studies will be encouraged to examine diabetes therapy, including the impact of memory and other cognitive deficiencies often experienced by the elderly, problems associated with age-related decline in olfactory

and gustatory senses with consequent effects on dietary discipline and appetite in the elderly diabetic, and influence of cultural beliefs and attitudes toward medical care. Studies on the influence of co-existing pathologies on medical and dietary management are especially important in the elderly diabetic who may suffer a number of diseases.

National Institute of Child Health and Human Development

The Institute's special focus in diabetes will be in the following areas of research: 1) diabetes during pregnancy and its effects on infants; 2) the effects of infant feeding on the development of obesity; 3) the behavioral development of offspring of diabetic mothers; 4) studies of genetic predisposition to juvenile diabetes; and 5) the interrelationship of diabetes and oral contraceptives.

The Institute will continue to emphasize and encourage research in the areas of:

- Development of control of carbohydrate metabolism
- Developmental endocrinology
- Gestational diabetes
- Infant mortality, congenital defects, and perinatal morbidity in infants of diabetic mothers
- Ascertainment of risk factors in infancy and childhood for Type I and Type II diabetes mellitus later in life
- Influence of feeding and weaning practices on development of obesity and insulin resistance in infancy and childhood
- Influence of oral contraceptives on risk of glucose intolerance
- Genetic and immunological aspects of Type I and Type II diabetes mellitus.

The National Institute of Child Health and Human Development (NICHHD) will continue to expand its Major Research Programs effort, which is aimed at the reduction of perinatal mortality and morbidity, and focus particularly on aspects of diabetes in pregnancy and on infants of diabetic mothers.

The National Institute of Child Health and Human Development plans to expand its program exploring nutritional antecedents of disease later in life, with a special emphasis being placed on certain aspects of obesity research, including: the development of insulin resistance; cerebral control of food intake; psychosocial determinants of excessive food intake and subsequent obesity; feeding and weaning practices in early life and their effects on carbohydrate metabolism and energy balance; and development of predictors of obesity and insulin resistance later in life (including biochemical and enzymatic profiles of populations of fat cells).

National Heart, Lung and Blood Institute

The metabolic effects and cardiovascular consequences of diabetes are studied as aspects of investigations focused on atherosclerosis, hypertension, coronary heart disease, peripheral vessel disease, arrhythmias, heart failure, shock, thrombosis, and

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lung disease in humans and animals. In addition, epidemiological investigations and clinical intervention trials on coronary heart disease include studies of diabetes as one of the several predisposing risk factors.

The Institute will continue to develop and conduct several major clinical intervention trials of the treatment and prevention of morbidity and mortality from coronary heart disease (CHD). In trials of the effect of a beta-blocking drug and on coronary artery surgery in the treatment of coronary heart disease, diabetic patients are included in the studies. In the Multiple Risk Factor Intervention Trial, insulin-requiring diabetics are excluded, but those with glucose intolerance or those who are managed without insulin are included in the study. Information of interest to the treatment and prevention of CHD among adult diabetics may arise from these extensive and long-term trials, which collectively involve about 34,000 participants.

The Institute will participate with the National Institute of Arthritis, Metabolism, and Digestive Diseases in the clinical trial to assess the effect of treatment of juvenile-onset diabetes on the development of micro- and macrovascular complications.

National Institute of Allergy and Infectious Diseases

The National Institute of Allergy and Infectious Diseases (NIAID) has a special concern for the medical problems confronting diabetics. Infections occur more frequently and in more serious forms in diabetics as a group, than in the general population. Many diabetics develop an allergic response to life-supporting doses of insulin. In addition, the National Institute of Allergy and Infectious Diseases is particularly concerned with the possible infections and autoimmune processes that play a role in the pathogenesis of certain forms of diabetes. The Institute will continue and expand its support of research in these areas.

The Institute will also expand its support of applied and developmental research on organ transplantation, as well as basic research on the mechanisms of immune recognition and graft rejection. Such research has the potential for making significant contributions to the treatment of diabetes through pancreas and pancreatic islet transplantation.

The Institute plans to increase its support of (1) a continued search for viruses that might cause diabetes, (2) development of beta cell cultures, and (3) studies of the role of anti-beta cell antibodies and cell-mediated immunity in the development of juvenile-onset diabetes.

The Institute plans to support research focused on the histocompatibility antigens (HLA) system in diabetes. HLA technology will be incorporated into epidemiologic and genetic studies of diabetes. The Institute will continue to provide support of HLA typing activity.

National Institute of Dental Research

The National Institute of Dental Research (NIDR) plans to support progress and research relating to peridontal disease in diabetes and 2) artificial sweeteners in the treatment of diabetes. The intramural program of research on viruses as an etiologic factor in certain types of diabetes will continue.

National Institute of General Medical Sciences

The National Institute of General Medical Sciences' (NIGMS) support of research on the development and cellular differentiation of the pancreas, and on the pharmacology of hypoglycemic agents and their effects in diabetes will continue. Support will also be provided for a diabetes cell collection in the Human Genetic Mutant Cell Repository.

National Institute of Neurological and Communicative Disorders and Stroke

The National Institute of Neurological and Communicative Disorders and Stroke (NINCDS) will continue to support basic and clinical research on the neurologic and cerebrovascular systems as they relate to the pathogenesis of diabetes and its devastating complications in the central and peripheral nervous system and the circulation.

OTHER PROGRAM PLANS

Consistent with the availability of funds, the Institute hopes to continue currently ongoing research efforts which are mentioned in the Opening Statement and in the Special Reports submitted during testimony, and to initiate additional studies which at this point in the state of the art appear to be promising approaches. The following are a few specific examples:

In arthritis, new research efforts will take advantage of the striking associations between genes in the major histocompatibility loci and the rheumatic diseases; B locus antigens in spondylitis and its variants, and D locus antigens in rheumatoid arthritis and systemic lupus. These provide genetic markers for disease predispositions to several forms of arthritis. Epidemiologic studies will be initiated in the spondylitic group, rheumatoid arthritis, lupus and juvenile polyarthritis. These will have been stimulated by a Workshop on Rheumatic Diseases Epidemiology to be held in FY 1980. Continued support of the Arthritis Centers will be directed to insuring that each Center will develop each of its components to a state of excellence. Plans have been initiated by NIAMDD to develop mechanisms needed to evaluate continuously the effectiveness of the program.

In bone disease, in recent years, new techniques have promoted the study of bone structure and mechanisms of calcification. The interaction of calcium with bone matrix will be studied and efforts will be made to correlate functional activity with specific cell types. Such studies hold promise of producing therapeutic agents to stimulate bone synthesis for use in fracture healing. Another hopeful approach is the use of electrical currents or electromagnetic forces to induce healing of bone fractures that have remained open after usual treatment. This new therapy of electrical stimulation of bone will be the subject of a workshop in late 1979. Also, by FY 81 or FY 82 results will be available of an evaluation of research needs and priorities in bone diseases, planned by NIAMDD for FY 79 and FY 80; these will help set priorities for future research activities and manpower development.

In dermatology, utilizing new techniques of single sebaceous gland isolation, biochemical and physiologic studies of lipid synthesis and secretion in human sebaceous glands will be intensified to provide a more sound rationale for therapy of acne. Also, there is new information on the potential importance of retinoic acids in treating acne, and studies along these lines will be initiated and expanded.

Endocrinology is currently the subject of a Congressionally mandated evaluation of research needs. Recommendations of the study which will include the area of metabolism, will influence FY 81 and subsequent research activities which are expected to include work on hormone receptors and binding, biochemical, physiological and ultrastructural studies of hormone synthesis, secretion, and hormone-mediated transport processes and use of recombinant DNA techniques for hormone synthesis and for the study of genetic control of endocrine-related regulatory processes. Also, the Institute hopes

to expand modestly its support of its National Pituitary Agency to include new programs for the production and distribution of rare and generally unavailable hormones in addition to human growth hormone and related biological products.

In metabolic diseases, we hope, in particular, to expand the level of cystic fibrosis-related research efforts. Also, basic research on the function, chemical structure, and mechanism of regulation of the synthesis of glycoprotein hormones and on the mechanism by which calcium and other cations influence and control key regulatory processes--including enzyme action, secretory processes, and cellular hormonal effects--will be emphasized. More knowledge in depth about these basic processes is essential for more rapid progress against cystic fibrosis and may have considerable value in other metabolic diseases not now evident.

In digestive diseases, recent findings have implicated viruses and an "L-form" of bacteria as "candidate" agents in the causation of Crohn's Disease. Intensive studies will be undertaken to determine whether one of these, or another infectious agent, is indeed involved. The technology for precise measurement of gastrointestinal hormones, the availability of these in relatively pure form, the development of methods for culture of single cell types and the technology for measuring cell multiplication will be utilized to study the effect of these hormones on the turnover of gastrointestinal cells. Also, a comparison of conventional x-ray studies and endoscopy in the diagnosis of peptic ulcer is planned. Factors such as dollar costs, side effects, discomfort, and patient acceptance will be considered, together with a controlled determination of which procedure is most effective in detecting the presence of an ulcer in different locations and at different stages.

In liver disease, evaluation and standardization will be conducted of new techniques in the diagnosis of hepatic and pancreatic diseases and on the use of transendoscopic manipulation and operation on the sphincter of Oddi and the biliary ducts for diagnosis, relief of common duct obstruction and removal of gallstones. To aid in preventing or effectively controlling portal hypertension to decrease mortality due to cirrhosis, researchers will seek reliable, non-invasive methods of measuring portal pressure and hepatic blood flow.

In nutrition, new information will be sought on requirements and safe levels of nutrients for maintenance, growth, development and well being at different stages of the life cycle and for various conditions, including stress, drug use, nutrient imbalances and different activity levels. We also hope to study the long-term consequences of changing dietary patterns and food habits and suggested relationship between diet and various health disorders. Also, initiation of several new Clinical Nutrition Research Units is contemplated.

In kidney and urologic diseases, genetic, prenatal, developmental, and animal studies related to polycystic renal disease will be initiated. Because the ingestion of excessive amounts of certain analgesics and/or a combination of aspirin and

phenacetin over long periods of time has been found to result in severe renal disease, new studies are planned in this area. In end-stage renal disease research, emphasis will be on pathophysiology of uremia, causes of end-stage renal disease, new treatments such as inexpensive continuous ambulatory peritoneal self-dialysis, improved peritoneal dialysis, the safety of reusing disposable dialyzers, and exploration of the feasibility of utilizing dietary means to postpone onset of maintenance dialysis and of reducing its frequency in chronic renal patients.

In hematology, emphasis will be placed on efforts to stimulate endogenous erythropoietin production and to accomplish effective replacement with exogenous erythropoietin in the search for alleviation of the anemia of uremia. New studies will be initiated on the interactions among T cells, B cells and macrophages in response to antigens. Also, a better understanding of iron pools, iron exchange and metabolism of iron chelates will be sought.

PRIORITIES

Senator SCHWEIKER. Your Institute, as you well know, has more programs, and also lobbyists talking to you than any other Institute.

Unfortunately, this is the year where we may have to tighten our belts and look at our priorities.

What kind of priority system would you use, Dr. Whedon, for possible breakthroughs, or what new efforts should be initiated and also for the record—well, let me ask you that on the record.

Are there any particular areas where you feel that investing in some effort might be very productive, realizing that there are so many diseases?

Dr. WHEDON. Indeed, it is a very difficult question.

Senator SCHWEIKER. Maybe you want to do that for the record.

Dr. WHEDON. Well, may I say on the record that it is particularly difficult, I think, as you have characterized it, on a standpat budget. You were talking earlier about a 250 pay line, and actually we estimate that with the President's budget, that the pay line cut-off would be nowhere near 250. It would be below 200. It might be somewhere around 170. So when one gets into a situation where you can pay only grant applications with scores as high as that, in other words, between 100 and 170, it is going to be extraordinarily difficult to make choices. Because the ones we pay will be of very, very high quality in all programs.

Senator SCHWEIKER. Your pay line for diabetes would be what, this year?

Dr. WHEDON. This year we estimate that the mean for all institute programs will be 195 in 1979.

Senator SCHWEIKER. Are you talking about the Institute?

Dr. WHEDON. Yes.

Senator SCHWEIKER. How would arthritis and diabetes break down?

Dr. WHEDON. Those two programs you mean?

Senator SCHWEIKER. Yes.

Dr. WHEDON. Diabetes will probably pay to a higher pay line, but arthritis will be able to go no further than the mean.

Senator SCHWEIKER. Where will the new budget take you?

Dr. WHEDON. Down to 170.

IMPACT OF 5-PERCENT CUT

Senator SCHWEIKER. Where would the 5-percent cut take you?

Dr. WHEDON. That I have not estimated with any accuracy.

Dr. FREDRICKSON. The funding level would remain about the same, Senator Schweiker. If we must take a 5-percent cut our intention is to retain the same purchasing power for new grants. In order to do this, we would have to go to all the noncompeting continuing grants, and take away portions of their budget. So we would be funding to about the same priority score.

Senator SCHWEIKER. When I asked you about these figures, you told me there was roughly a 50-percent cut in new grants this year.

Dr. FREDRICKSON. In new grants, that is correct, sir. I indicated there was a smaller percentage reduction in total grants. But it is from the noncompeting grants that we would have to get the money to maintain the pay line.

Senator SCHWEIKER. But you didn't do that—you did just the opposite this year.

Your noncompeting grants went up 2,000 grants, and your competing grants went down 200, with a standstill budget.

Dr. FREDRICKSON. That is correct, Senator Schweiker, because we do not propose, even in this level budget, to take any money away from continuation grants. It is a very bad thing to do, and it destabilizes the system. But we would have to do that with a 5-percent reduction.

Senator SCHWEIKER. But with a 5-percent cut, then, you would take more?

Dr. FREDRICKSON. We would have to go into the noncompeting lines, that is correct.

Senator SCHWEIKER. But you wouldn't be able to maintain the competing ones, either? You sort of implied you wouldn't hurt the competing ones. But to some extent a standstill budget hurts the competing ones.

Dr. FREDRICKSON. We would try to maintain the level of the request regardless.

Senator SCHWEIKER. I see.

I was wrong in my arithmetic, Dr. Fredrickson. It is a 2,600 cut in competing grants, which is a reduction of almost 50 percent. I was wrong. I did my quick arithmetic incorrectly. It is reducing 5,673 competing grants to 3,062, a 2,600 cut. You are saying that you probably would not take competing grants down any further if your budget were cut 5 percent below the President's figures, you would go after noncompeting grants?

Dr. FREDRICKSON. If we took a 5-percent reduction, we would reduce the noncompeting grants, in order to have the capacity to fund a certain number of competing.

Senator SCHWEIKER. The noncompeting projects go from one year to another?

Dr. FREDRICKSON. For approximately 3 years.

Senator SCHWEIKER. So we must have had an increase 3 years ago.

Dr. FREDRICKSON. We had one last year, too, sir.

NATIONAL COMMISSION ON DIGESTIVE DISEASES

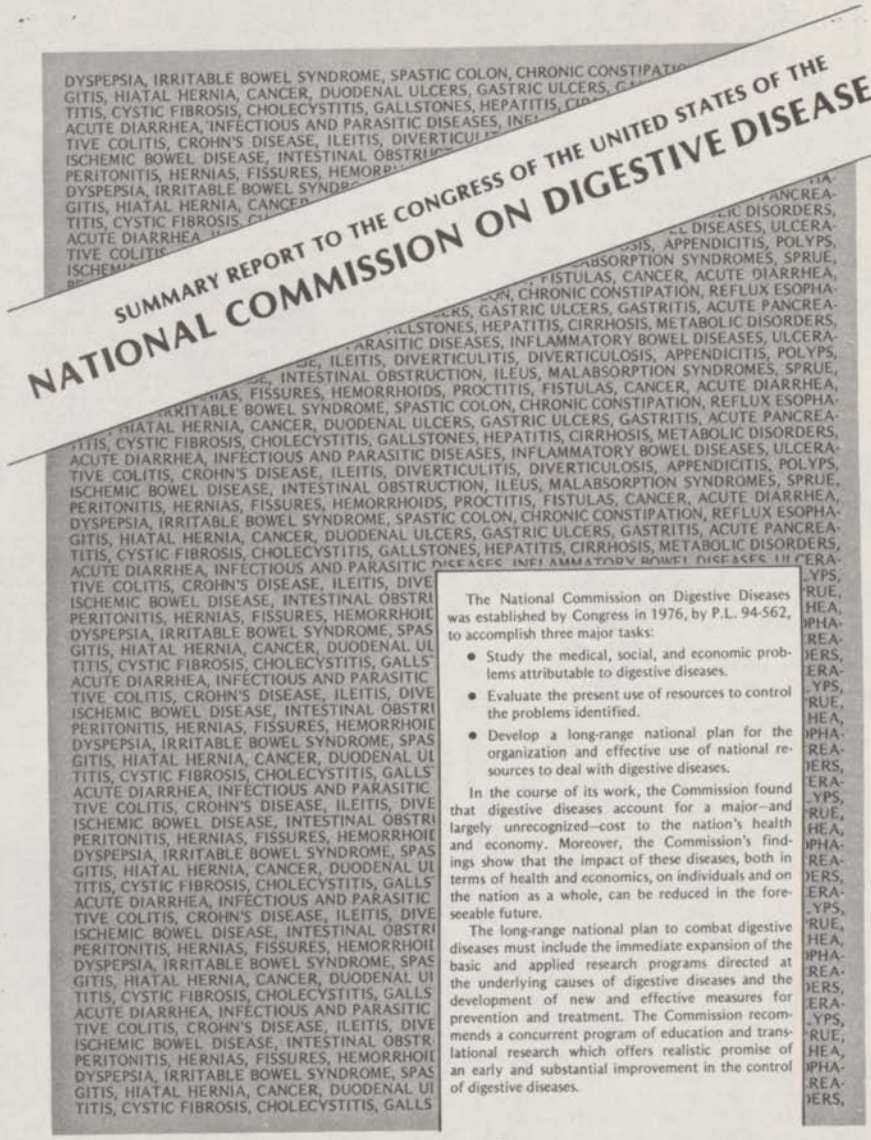
Senator SCHWEIKER. As you know, Dr. Whedon, The National Digestive Diseases Commission has submitted a report to the Congress.

Would you give us some response to that report's recommendations, and describe how your budget provides or doesn't provide for implementing the Commission's report?

Dr. WHEDON. The Commission has a series of recommendations which are summarized in a four-page handout, which I would be pleased to submit for the record, if I may.

Senator SCHWEIKER. Yes. I think we should put it in the record.

[The information follows:]


SUMMARY REPORT TO THE CONGRESS OF THE UNITED STATES OF THE
NATIONAL COMMISSION ON DIGESTIVE DISEASES
The National Commission on Digestive Diseases was established by Congress in 1976, by P.L. 94-562, to accomplish three major tasks:
• Study the medical, social, and economic problems attributable to digestive diseases.
• Evaluate the present use of resources to control the problems identified.
• Develop a long-range national plan for the organization and effective use of national resources to deal with digestive diseases.
In the course of its work, the Commission found that digestive diseases account for a major—and largely unrecognized—cost to the nation's health and economy. Moreover, the Commission's findings show that the impact of these diseases, both in terms of health and economics, on individuals and on the nation as a whole, can be reduced in the foreseeable future.
The long-range national plan to combat digestive diseases must include the immediate expansion of the basic and applied research programs directed at the underlying causes of digestive diseases and the development of new and effective measures for prevention and treatment. The Commission recommends a concurrent program of education and translational research which offers realistic promise of an early and substantial improvement in the control of digestive diseases.

FINDINGS OF THE COMMISSION

While digestive diseases vary in severity from brief, self-limited illnesses to chronic, disabling, and some universally fatal conditions, their total social and economic impact is enormous. Measured in terms of morbidity, mortality, and cost, they constitute *the third largest component of the total economic burden of illness in the United States*, being outranked only by circulatory diseases and by the combined category of accidents, poisonings, and violence.

Digestive diseases collectively represent:

- 10 percent of the total economic burden of illness in the United States, as defined by the National Center for Health Statistics.
- The primary reason for major surgery.
- The leading cause of hospitalization.
- 15 percent of all hospital utilization (43.4 million hospital days each year).
- The second most prevalent cause of disability among the employed.
- 20 million chronically ill individuals.
- 14 million persons who suffer acute episodes of illness each year.
- 190,000 deaths each year (counting only those for which digestive diseases are identified as the *immediate* cause of death).
- $17 billion in direct health care costs.
- $35 billion in total annual economic loss, or approximately 1.5 percent of the gross national product (1978 projection).

Digestive diseases are highly detrimental to Americans in their peak years of productivity and responsibility. Seventeen of every 100 individuals between the ages of 45 and 64, most of whom sustain family income in whole or in part, have some form of diagnosed digestive disease. At the same time, the absolute importance of digestive diseases as causes of serious illness, hospitalization, and death is highest among the aged.

Digestive diseases abound in all strata of our society and in all parts of the United States. Their diagnosis and treatment often depend upon the ready availability of sophisticated instruments and highly trained personnel. Thus, the burden of digestive diseases can be expected to fall more heavily on our rural population, where the low population density cannot support expensive equipment and specialists, and where physical distances between physician and patients are often great.

The figures cited above, however, fail to convey the social and financial devastation experienced by people afflicted with the most severe and chronic forms of digestive diseases. For these people, frequent consequences may be prolonged debility, malnutrition, unemployment, denial of insurance protection, and lifetime medical expenses as high as $500,000 for an individual patient.

In contrast to the magnitude of these problems, *efforts to control digestive diseases have been tragically inadequate* and needlessly fragmented. This is due in part to public attitudes and to minimum public awareness of preventive measures and the consequences of neglect. The digestive tract and its functions are viewed through veils of ignorance, embarrassment, taboo, and inappropriate humor.

Efforts of concerned voluntary organizations which have worked hard and long to increase patient and public understanding of digestive diseases are noteworthy. They have demonstrated over the years that changes in public attitudes through education are both possible and vitally necessary.

As a subject of academic concern, digestive diseases are underrepresented on the faculties of medical and other professional schools, and the number of active researchers in the field is not only relatively small, but is also declining. The decline is related to current limitations on the level and the stability of support for digestive disease research, which has discouraged talented young physicians and scientists from pursuing research careers in this field. Meanwhile, established investigators have left research in the digestive diseases and are not being replaced.

Despite the relatively low level of research support, significant advancements have been made in the state of knowledge about a number of common digestive diseases, their treatment, and their prevention. Major benefits have been achieved for patients with hepatitis, peptic ulcers, gallstones, infectious diarrhea, diseases of absorption, reflux esophagitis, gastrointestinal bleeding, aspirin-induced stomach injury, and colonic polyps, as well as for patients requiring parenteral nutrition and major surgical intervention. Much work remains to be done, however, in terms of both prevention and treatment of these disorders, and there are still many diseases for which effective modes of diagnosis and treatment are entirely lacking.

THE NATIONAL PLAN

The National Commission on Digestive Diseases strongly believes it is time for the nation to mount a vigorous and well-coordinated attack on digestive diseases. The national plan presented in Volume I of the report of the National Commission on Digestive Diseases includes a series of interrelated goals and strategies. They incorporate the most promising leads in research and needed new directions in health care delivery and education. All components of the plan can and should be implemented without delay, with the expectation that benefits to the public will be

evident and measurable in varying stages in one to 10 or more years.

Since so much remains unknown about the causes, mechanisms, and factors influencing digestive diseases, the essential foundation of the long-range plan is a well-coordinated, expanded research endeavor. Research offers the surest and most cost-effective means of substantially reducing the suffering and the economic burdens resulting from digestive diseases. In the meantime, as research progresses, the immediate needs of patients with digestive diseases must not be overlooked; these needs are addressed directly in the long-range plan.

The Commission has developed the long-range plan to achieve two major goals:

- Reduce the suffering of all Americans afflicted with digestive diseases.
- Reduce the costs associated with digestive diseases.

In an era of escalating health care needs and limited resources, only a well-organized, detailed, cost-effective program directed at a clearly identified social goal can justify sustained public support. The long-range plan developed by the Commission, we believe, is such a program. Minimum budget increments to implement these programs are proposed.

The recommendations listed below have been carefully considered for their feasibility, cost, and expected benefits. They represent, in essence, the Commission's conclusions in terms of: (1) immediate action that promises early and lasting benefits, (2) programs that are imperative for the public good in the long-range effort to combat digestive diseases, (3) proposals that are not aimed solely at problems related to digestive diseases but are inclusive of other major national health needs, and (4) steps essential to the coordination and organization of the long-range plan.

THE SCOPE OF DIGESTIVE DISEASES

The digestive tract, which includes the esophagus, stomach, intestines, gallbladder, liver, and pancreas, is affected by a wide range of acute and chronic diseases, including infections, cancers, intoxications, and diseases of unknown origin. Digestive diseases are disorders of any of these organs. Some of them are commonly known, such as ulcers, hepatitis, and gastrointestinal cancers; others, such as biliary atresia, cystic fibrosis, inflammatory bowel diseases, and pancreatitis, occur less frequently but with devastating long-term effects.

RECOMMENDATIONS OF THE COMMISSION

The National Commission on Digestive Diseases recommends that Congress and concerned agencies, public and private, take the following actions immediately to provide early and continued benefits in the national effort to combat digestive diseases.

Measures to improve the provision of information and training to patients, health care personnel, and the public:

1. Establish and fund a National Digestive Diseases Education and Information Clearinghouse to improve wide distribution of available knowledge in prevention and control of digestive diseases.
2. Promote the establishment of standards for the education and training of specialists in digestive diseases.
3. Strengthen and, where necessary for this purpose, fund educational programs in digestive diseases in American medical schools.

Measures to improve medical care of patients with digestive diseases:

4. Standardize the nomenclature, diagnostic criteria and methodology, and guidelines for measuring disability caused by digestive diseases.
5. Develop guidelines for the sequence of performing diagnostic tests in the digestive diseases.
6. Increase funding for the study of risk-benefits and cost-benefits related to health care services for patients with digestive diseases, and for translational research—the translation of known medical knowledge into effective treatment.
7. Expand programs in digestive diseases in the Department of Defense.
8. Expand clinical research in the digestive diseases and programs for the treatment of these diseases in the Veterans Administration.

Measures to promote research in needed and promising areas:

9. Enlarge and strengthen Federal training programs in research on digestive diseases to increase the number of teacher-researchers and to encourage the interest of larger numbers of young scientists in this vital area of research.
10. Increase funding for applied (clinical) research on such topics as adverse drug reactions, alcoholic liver disease, cirrhosis, colonic disorders, functional gastrointestinal diseases, gallstones, gastrointestinal bleeding and vascular disorders, gastrointestinal surgery, hepatitis, infectious

diarrheas, inflammatory bowel diseases, maldigestion and malabsorption, malignancies (cancer) of the digestive organs, pancreatitis, pediatric digestive diseases, peptic ulcer, reflux esophagitis and esophageal motility disorders.

The Commission recommends that simultaneously with the actions in Recommendations 1 through 10, Congress and the respective concerned agencies take the following specific actions to ease the national burden caused by digestive diseases in the foreseeable future and to establish a long-range, national program of continuing and coordinated research in digestive diseases:

11. Increase funding for basic research in digestive diseases to lay firmer foundations for their prevention, diagnosis, and treatment.
12. Fund cooperative research in digestive diseases when scientifically necessary and cost-effective.
13. Expand the intramural digestive disease research programs at the National Institutes of Health.
14. Determine epidemiological patterns of digestive diseases to formulate a comprehensive understanding of their impact on the population's physical, emotional, and financial well-being.
15. Study the effects of environmental and industrial pollutants on organs of the digestive system.
16. Fund research on the critical role of diet as a cause of digestive diseases.

The Commission recommends that the Congress or appropriate agencies undertake the following steps with regard to diseases in general, but with specific emphasis on digestive diseases:

17. Survey manpower requirements for the prevention and treatment of digestive and related diseases and study the cost-effectiveness of various forms of professional training.
18. Assure that the cost of educating patients about their digestive diseases is a direct reimbursable expense by Federal and private insurance programs.
19. Enact legislation to provide catastrophic health insurance coverage for all citizens.
20. Exempt from the Office of Management and Budget clearance procedures those medical and behavioral research projects which are conducted in accordance with specified protocols which are approved under DHEW regulations for the protection of human subjects, and which call only for voluntary participation; and exempt the digestive diseases workshops recommended in this report from the DHEW policy which reduces the number of conferences.

The Commission recommends that the Congress and/or appropriate Federal agencies, in order to organize and coordinate the long-range plan outlined in this report, take the following actions:

21. Establish a National Digestive Diseases Advisory Board responsible to the Congress and the Secretary of Health, Education, and Welfare.
22. Appoint knowledgeable representatives concerned about the problems associated with digestive diseases and the implementation of solutions to those problems to the Advisory Councils of the National Cancer Institute, the National Institute of Allergy and Infectious Diseases, and the National Institute of Alcohol Abuse and Alcoholism.
23. Enhance the status of digestive diseases within the National Institutes of Health by forming a Division of Digestive Diseases within the National Institute of Arthritis, Metabolism, and Digestive Diseases.

Dr. WHEDON. There are a variety of suggestions, including, as one would imagine, a more vigorous support of research in this area and I might say, not just for this institute, but also for a number of other institutes, particularly the National Cancer Institute, the National Institute of Allergy and Infectious Diseases, particularly, and to some extent the National Institute of Child Health and Human Development, because of the extent to which digestive diseases impact the problems and the opportunity for research of these Institutes. The 1980 budget proposed does not provide for the recommendations of the Commission.

The Commission recommended establishment of a Digestive Diseases Information Clearinghouse, which we shall endeavor to do, and they expressed needs for a number of other activities, including a desire to expand the intramural research program that we have in digestive diseases in our Institute.

COMMUNITY PROJECTS ON ARTHRITIS

Senator SCHWEIKER. As noted in the committee report for last year, although funds are authorized for the development of community projects under the National Arthritis Act, no appropriations have been made because of a lack of initiative shown to establish them.

What response have you made to this directive, and what are your plans for the fiscal year on that?

Dr. WHEDON. There are ongoing plans in this respect which will be continued into 1980, and this is to support some community project activities, but they will all take place within the Arthritis Multipurpose Center. I think this is the best location for this activity to take place. It would be in coordination with investigators and other physicians of high quality, and we will get the most for our money by undertaking these community projects in the centers.

Senator SCHWEIKER. Thank you very much, Dr. Whedon.

QUESTIONS SUBMITTED FOR RESPONSES

[The following questions were not asked at the hearing, but were submitted to the Department for response subsequent to the hearing:]

RESEARCH ADVANCES

Question: Dr. Whedon, please share with the committee what you consider to be the most important advances made with funds provided by the Institute in the area of biomedical research.

Answer: I assume reference is being made to this last year only. Even so, it is difficult to describe each of the important advances we have supported. The following, therefore, are some pertinent, brief examples.

In the area of bone diseases, a new technique which utilizes pulsing electromagnetic fields and which does not require electrode implantation or high voltages, was studied by an Institute-supported investigator who achieved complete healing of previously recalcitrate bone fractures in 90% of a group of thirty children with congential or acquired refractory bone fractures; complete union of resistant fractures has also been produced in 85% of seventy adults treated with this technique.

Progress continues actively to elucidate the basic mechanisms responsible for initiating or perpetuating tissue destruction in rheumatoid arthritis. Among these, certain types of prostaglandins produced by soft joint tissues are found to play a vital role in joint and bone destruction.

In reference to Diabetes, this year saw the production of a synthetic insulin which is identical to human insulin; this development holds potential for future production of pure human insulin for treatment purposes. A forerunner of this work was the artificial creation, in bacteria, through the use of recombinant DNA techniques, of a form of rat insulin by a team of NIH supported scientists at Harvard University.

One new research development in the area of Cystic Fibrosis which we shall be following closely, involves confirmation of previous findings that cultured cells from cystic fibrosis patients are more resistant than normal cells to the toxic effects of dexamethasone; this phenomenon may be useful in the future prenatal diagnosis of cystic fibrosis and in identifying asymptomatic carriers of the cystic fibrosis trait.

High on the list of research interests in the area of Digestive Diseases are studies of inhibitors of stomach acid secretion; through a multicenter study a grantee of the National Institute of Arthritis, Metabolism, and Digestive Diseases (NIAMDD) has demonstrated that cimetidine, an antihistaminic drug, which has recently been approved for use by the Food and Drug Administration, has the capacity to produce duodenal ulcer healing and pain relief equivalent to that afforded by an intensive regimen of liquid antacid. Also research efforts continue to evaluate the safety and efficacy of chenodeoxycholic acid for gallbladder stone dissolution and prevention, on a long-term oral use basis.

Following the discovery that not all individuals can handle efficiently lactose ("milk sugar") in their adult years, grantees of the NIAMDD studied lactose tolerance in lactase-deficient American Indians to determine implications for consumption of

nutritionally useful quantities of milk without the appearance of significant gastro-intestinal symptoms. It was found that lactase-deficient American Indians can tolerate well a small amount of lactose equivalent to that contained in 1 to 1.5 glasses of milk taken with a meal.

Also, under Institute support, an investigator has demonstrated that cholestyramine, an anion exchange resin, binds chlordecone (Kepone) in rat intestine, increases its excretion, decreases tissue concentration, and holds high promise for treatment of human poisoning by Kepone or other lipophilic (accumulating in fatty tissues) environmental toxins.

The Kidney, Urologic and Blood Diseases Program of the Institute has completed an Evaluation-Study of Research Needs in Nephrology and Urology (DHEW publication No. NIH 78-1481 to 1485) which provides information on the state of the art and indicates areas where new research is to be encouraged; in addition, a monograph on Prevention of Kidney and Urinary Tract Diseases has also been recently published. In terms of chronic renal diseases, an improvement in kidney transplantation technology is sought while continued emphasis is placed on reduction of cost and increased clinical effectiveness of dialysis while searching for novel therapeutic approaches. In this respect a promising improvement in the technique of peritoneal dialysis is the new and relatively inexpensive technique of continuous ambulatory peritoneal dialysis (CAPD) which at present is undergoing further investigation through Institute-sponsored research.

In the Hematology Program of the Institute major efforts are devoted to generate a great deal of basic information which is needed to understand the basic biology of blood and its cellular constituents as well as the many hematologic disorders. One group of Institute grantees has reported already the identification of specific hemoglobin gene sequences in amniotic fluid-cell cultures, thus affirming the feasibility of these methods of prenatal diagnosis for thalassemia, a form of inherited anemia. A second group of grantee-scientists used restriction enzymes to map the DNA sequence of genes in order to find the structural abnormality associated with sickle cell gene mutation. Employing amniocentesis to test fetal cells, these scientists using their new method, succeeded in determining before delivery that several black couples who were known carriers of sickle cell anemia would not pass the disease on to their unborn children.

Naturally, those are just a few highlights of the many achievements of the Institute during this last year; more detailed special reports have been submitted in the areas of Digestive Diseases, Cystic Fibrosis, Kidney Diseases, Diabetes and Arthritis.

Question: What do you see in the near future?

Answer: A continuation of our research efforts and introduction into practice, on a larger scale, of the innovation which these research efforts have brought about. Cimetidine for duodenal ulcer and continuous ambulatory dialysis in chronic end-stage renal disease are two examples of developments which will be given particular research attention in the near future.

ARTHRITIS ADVANCES

Question: What kinds of advances have we made in the last ten years in the area of arthritis?

Answer: Many of the advances that have been made are summarized in a special, mandated report entitled, "Progress Against the Rheumatic Diseases, 1967-1977," which the NIAMDD submitted to the Senate Committee on Appropriations. Accomplishments noted in this report include the following:

- Development of a new prosthetic knuckle that enables people with deformed and crippled hands to grasp and pinch once again.
- Demonstrable success of joint replacement (with prosthetic joints) particularly in the major weight-bearing joints such as hips and knees.
- Progress in treating certain rheumatoid arthritis patients with intramuscular injection of gold salts.
- Development of therapeutic drugs, such as indomethacin and phenylbutazone, for patients with ankylosing spondylitis, or spinal arthritis.
- Improved survival rates for children and adults with systemic lupus erythematosus.

In addition, the clinical management of patients who suffer from gouty arthritis has greatly improved in recent years. Once the patient has been identified, proper drug therapy can help to treat and prevent painful attacks, as well as prevent further progression of this disease.

Despite these and other advances, however, we still lack the knowledge to develop a means of preventing some of the most important types of arthritis, such as osteoarthritis and rheumatoid arthritis. We have yet to learn what triggers arthritis, or what causes or may prolong remission. Problems of toxicity often accompany new drug therapies for rheumatic diseases, a recurring clinical difficulty that can only be addressed by further research. While major strides have been made in perfecting joint replacements, wear and corrosion of materials can occur over long periods of time. Thus, studies continue to seek the best materials for fabricating these artificial joints. In short, research has made important contributions to combating arthritis and other rheumatic diseases during the past ten years, but a tremendous amount of additional research needs to be done.

INSTITUTE INTERACTION

Question: Dr. Whedon and Dr. Krause, who is the Director of the Allergy Institute: We are told that possibly infectious and other environmental factors play a large role in arthritis. Would you comment on this for us, please, and tell us what you are doing in terms of inter-Institute cooperation in this area.

Answer: Certain acute, self-limited forms or manifestations of arthritis may be associated with such viral infections as rubella, smallpox, and hepatitis. We also know that bacteria may

invade joint membranes and fluid, resulting in acute, infectious arthritis. Individuals particularly susceptible to bacterial arthritis include sickle-cell anemia patients, the elderly, and the chronically ill. Diagnosis of viral or bacterial arthritis is usually made by confirming the presence of infectious agents in extracted joint fluid. Treatment includes use of antibiotics, surgical drainage of infected areas, or both.

While it has been suggested that viruses or bacteria may also be implicated in chronic arthritis, present findings in support of this theory are largely inconclusive. This area of investigation is highly active, however, and both the National Institute of Arthritis, Metabolism, and Digestive Diseases and the National Institute of Allergy and Infectious Diseases are conducting studies that may help to determine whether infectious agents play a role in several different forms of chronic arthritis and connective tissue diseases.

In NIAMDD, researchers are investigating the action of bacteria such as salmonellae and mycoplasma in animals with experimentally induced arthritis. Related work focuses on rubella in man, as well as an identification of a possible infectious agent in rheumatoid arthritis.

National Institute of Allergy and Infectious Diseases-supported investigators are exploring streptococcus infections in relation to rheumatic fever. In another study, researchers are examining "slow viruses" -- a recently identified class of unconventional infectious agents -- in animal models that stimulate the human arthritis state.

Inter-Institute cooperation in this area is substantial, as evidenced by frequent joint publications by NIAID and NIAMDD intramural scientists. Both Institutes are, moreover, supporting preclinical and clinical research into a possible viral cause of lupus erythematosus, a grave rheumatic disease, of young women.

STATE PROGRAMS

Question: Many states are now establishing task forces and study groups to determine just what the problems in their areas are in terms of arthritis and related diseases. One such group is the Wisconsin Task Force on Arthritis which was asked to identify the health, social, educational, and economic needs of the state's 658,000 citizens suffering from arthritis and related diseases. What are you doing to foster more programs like this?

Answer: The Wisconsin Task Force has been extraordinarily successful in unifying arthritis-related programs within the state and in stimulating cooperation among various agencies and organizations. While it is not within our research-oriented mission to fund state programs such as the Wisconsin one, we are pursuing similar objectives within selected academic institutions that house our multipurpose arthritis centers. In accord with the National Arthritis Plan, the Institute is presently funding 24 multipurpose arthritis centers, which are dispersed geographically throughout the nation. Grants awarded to these centers are furthering coordinated programs in three areas:

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education of health professionals, patients and the public; basic and clinical research; and community demonstrations of new approaches to care for patients with long-term, disabling diseases.

Question: What type of support do you give to this?

Answer: Programs such as that initiated by the Wisconsin Task Force on Arthritis are usually supported at the state or local level, or by voluntary organizations. Certainly, however, the Institute encourages interaction between its multipurpose arthritis centers and state programs of this type.

Question: What plans in the future do you have in terms of helping them?

Answer: While it is not within the purview of this Institute to provide funding support to such programs, the new NIAMDD Arthritis Information Clearinghouse can further work in this area by apprising interested individuals and organizations of the success achieved through the Wisconsin model.

Question: In the long range, how do you feel these programs will impact on arthritis care and what are you doing to insure that such programs are coordinating their efforts?

Answer: In my opinion, programs such as the one in Wisconsin can have a long-term positive impact on arthritis care, not only by focusing attention on the needs of patients with this disease, but also by encouraging strong, unified efforts among the various agencies and organizations addressing the socioeconomic, educational, and health issues associated with arthritis. I believe that one way to foster coordination among such state programs is timely information exchange. As noted previously, the NIAMDD Arthritis Information Clearinghouse can make major contributions in this regard.

OSTEOARTHRITIS

Question: Why isn't more research being done in the area of osteoarthritis, or degenerative joint diseases, the most common form of arthritis which affects an estimated 16,000,000 persons and is one of the leading causes for social security disability payments being so high?

Answer: During Fiscal Year 1980, the Institute will direct an estimated $37 million toward research on arthritis and musculoskeletal diseases. Approximately $1 million of this amount will be applied directly to studies of osteoarthritis, while much of the remainder will support fundamental studies that are intended to yield results relevant to osteoarthritis. The NIAMDD shares your concern about the high prevalence of this disease, and is working to reduce the personal and economic burdens associated with osteoarthritis. We are strongly committed to research in this area, and believe that progress is being made. For example, NIAMDD-supported scientists at Harvard University have found the enzyme collagenase (an enzyme which can digest and dissolve collagen - the basic structural protein of connective tissue), and an inhibitor of collagenase, in osteoarthritic cartilage. These

findings suggest that locally synthesized collagenase may be implicated in degradation of bone cartilage associated with end-stage osteoarthritis. This study, as well as other work on the histology and chemical response of cartilage in relation to bone tissue, is helping to advance our understanding of the progressive nature of degenerative bone disease. Thus, within its resource capabilities, the Institute is conducting intensive studies in the area of osteoarthritis.

BRITTLE BONE DISEASE

Question: Could you tell us at this time whether or not you have any clinical studies going on in terms of brittle bone disease?

Answer: Brittle bone disease is the popular term for Osteogenesis Imperfecta, a disease in which failure of bone to form normally can lead to multiple bone fractures, hearing loss, and other severe problems in infants and young children. NIAMDD is actively supporting research on the basic mechanisms of normal and pathologic bone metabolism and development, and through this channel, new knowledge essential to the disease is being developed. At present, however, there are no ongoing studies of Osteogenesis Imperfecta involving patients.

Question: How much money do you expect to spend on brittle bone disease disorders in Fiscal Year 1979 and what are your plans for 1980?

Answer: The Institute is quite aware of the Committee's interest in osteogenesis imperfecta and related bone diseases and wishes to assure the Committee that these disorders are of major interest to us. Research in this area is being encouraged by program announcements and will be supported as heavily as is feasible in relation to quality grant applications. During Fiscal Year 1979, NIAMDD will award approximately $2.6 million for research in this area, including osteogenesis imperfecta, osteoporosis and related basic studies; the comparable figure for Fiscal Year 1980 is estimated to be $2.8 million.

WORKSHOP ON OSTEOPOROSIS

Question: I understand that your Institute sponsored a strategy workshop on osteoporosis about a year ago. Can you tell us what recommendations came out of this workshop and how your fiscal year 1980 budget reflects on these recommendations.

Answer: This workshop, held in February 1978, convened investigators active in bone cell biology, bone chemistry, and clinical studies of various diseases of the bone. A major recommendation of workshop participants was expansion of basic research in bone cell biology in order to exploit recent advances in understanding the interaction of environmental factors in bone cells. It was also recommended that special attention be paid to developing agents for reconstituting the skeleton in diseases of reduced bone cell mass. The Institute will attempt to be as

responsive as possible to these and other recommendations of the workshop within the context of the fiscal year 1980 budget which, in current dollars, is essentially comparable to our fiscal year 1979 funding level.

ROSALIND RUSSELL CENTER

Question: In 1979, separate funds were awarded to help renovate and equip the Rosalind Russell Memorial Arthritis Center. Has the renovation of this Center been completed? And what plans do you have for this Center in the future?

Answer: On December 4, 1978, the Institute received a proposal from the University of California at San Francisco to house the Rosalind Russell Memorial Arthritis Center at the San Francisco General Hospital. Funds were requested to renovate one complete floor of this facility for the Memorial Center, as well as for purchase of equipment. The application was for a supplemental award to enhance the activity of an ongoing Multipurpose Arthritis Center already funded by NIAMDD at the University.

The Institute convened an ad hoc group of expert consultants to review the application. Among the issues considered were the relationship between the proposed new facility and the ongoing project, such as opportunities for complementary efforts. As part of this review process, a site visit was also conducted, with favorable recommendations.

The proposal was subsequently approved by the NIAMDD National Advisory Council during its February 1 and 2, 1979, meeting. The Institute is now in the process of completing the award process to permit this Center to begin its important work in tribute to Rosalind Russell and her many contributions on behalf of arthritis patients and their families.

NUTRITION

Question: Last year, the Committee directed you and the other Institutes to establish and expand your Nutrition Programs. Please give us some specific examples of what you are doing in this area, and how you are coordinating your efforts with other Public Health Service Programs?

Answer: The Nutrition Program of the National Institute of Arthritis, Metabolism, and Digestive Diseases has enhanced its research efforts and priorities to cover studies in the areas of obesity, trace elements nutrition, dietary fiber, clinical nutrition trials including parenteral nutrition, basic mechanisms of action of dietary essential nutrients and factors that influence nutritional requirements. In fiscal year 1978 the plan and announcement for Core Grants for Clinical Nutrition Research Units (CNRUs) was developed, and it is expected that some grants for these units will be awarded during this fiscal year, 1979.

All the Institutes with nutrition-related activities are actively interacting through their representatives on the NIH Nutrition Coordinating Committee (NCC). This Committee is charged

with full coordination of all nutrition related activities within the NIH.

RENAL DIALYSIS COSTS

Question: Dr. Whedon, what progress has been made to decrease the cost of renal dialysis as a part of the general effort to decrease the cost of health care in this country?

Answer: The major development in this area relates to an innovative dialysis technique, chronic ambulatory peritoneal dialysis (CAPD), a technique which is used as an alternative to conventional hemodialysis. Suitable patients can do CAPD completely alone (self-care therapy); it does not require the use of any expensive dialysis equipment, specialized nursing care, electricity or plumbing. At present, CAPD's cost is comparable to that of home hemodialysis; nevertheless, it is expected that cost should significantly decrease. It is meant for all maintenance dialysis patients, but is a particularly invaluable dialysis technique for special groups such as patients with blood access problems, severe cardiovascular diseases, advanced age, diabetics and patients living alone or incapable of learning more complicated home hemodialysis techniques which involve complex machinery and methods.

Question: What role do you see that the NIAMDD played in this area?

Answer: Chronic ambulatory peritoneal dialysis (CAPD) evolved from a project sponsored by the Chronic Renal Diseases Program (former Artificial Kidney-Chronic Uremia Program) of the National Institute of Arthritis, Metabolism, and Digestive Diseases, and it is being fully developed at present, under the sponsorship of this Program.

Question: How much are we still spending on renal dialysis in the United States today?

Answer: By the end of 1977 the cost of maintenance dialysis care funded by the Federal government through Medicare, Medicaid and the Veterans Administration was approaching one billion dollars.

HEMATOLOGY

Question: Would you please share with us what the status is of the Drug Development Program to provide therapy for patients with Cooley's Anemia?

Answer: The only available treatment for thalassemic patients is chronic repeated transfusion, which, unfortunately, eventually results in severe and ultimately fatal iron storage disease. The NIAMDD since 1974 has organized and supported contract programs to develop new, more effective, iron chelating (binding) drugs, for clinical use, aimed at decreasing this iron overload. One such drug is ethylenediamine N, N1-dis [2-hydroxyphenyl] acetic acid, which is undergoing subchronical animal toxicity testing as a result of its promising chelating

ability and low toxicity. Some other compounds have shown hopeful signs of efficacy, and several classes of potential chelators have yet to be examined.

DIABETES FUNDING LEVEL

Question: In the last two to three years, the Committee has provided an additional $80 million for diabetes and related programs. In your opinion, at what level of funding should we be tackling this tragic disease?

Answer: Certainly, the additional funds recently provided have enabled the NIH to support a much larger proportion of highly meritorious research proposals and to make substantial progress in diabetes research, although the $165 million FY 80 funding level recommended for the NIH by the National Diabetes Commission has yet to be realized.

Concerning optimal funding for diabetes, or any other program area, I believe that resource levels should permit NIH support of the largest possible number of high-quality research proposals consistent with meeting the requirements of other national priorities. Funds should provide for research continuity, as well as for strengthening of programs, in real terms. We are concerned that major fluctuations in funding patterns can force investigators to forsake research careers, leading to long-term manpower shortages that are not readily remedied. Insufficient funding, particularly during inflationary periods--can result in lost research momentum and can preclude full and rapid pursuit of promising research leads. In diabetes, significant new research opportunities currently exist, including production of rat and human insulin through recombinant DNA technology; use of new, experimental techniques that prevent immunologic rejection of transplanted pancreatic islet cells from one strain of laboratory animal to another, and exploitation of recent advances in our understanding of the genetic pattern of inheritance in juvenile onset diabetes. Clearly, our ability to take advantage of these and other opportunities will be largely determined by short- and long-term funding levels.

DIABETES RESEARCH AND TRAINING CENTERS

Question: It is our understanding from a report submitted to the Committee by Secretary Califano that in Fiscal 1977 $5.4 million was provided for five Diabetes Research and Training Centers. How much are you funding these programs at in Fiscal 78 and 79? And what are your plans for Fiscal Year 1980?

Answer: In Fiscal Year 78, the NIAMDD directed approximately $7.9 million to the support of eight Diabetes Research and Training Centers. Funding estimates for Fiscal Year 79 and Fiscal Year 80 are that we expect to increase our support of these centers only modestly within the limits of our budget.

Support of the DRTC program will be in accord with projected commitments and plans for regular individual investigator-initiated research grants in the diabetes program, as well as in concert with an evaluation of the Centers Program.

Question: What do you hope to achieve through these Centers?

Answer: These Centers, which are built on an established base of high quality research grant support, are intended to achieve an optimal mix of research, training, educational, and "translation" activities. By providing a unifying environment for these distinct yet highly related functions, DRTC Centers help to encourage more rapid and complementary advances in preventing, diagnosing and treating diabetes.

ABSORPTION OF INSULIN

Question: Recently we are told that researchers have developed a suppository for administration of insulin for diabetics. Instead of the usual subcutaneous route, a suppository allows insulin to be absorbed into the blood stream through the rectum. Has the United States undertaken any studies of this method of treatment?

Answer: The NIH is not conducting studies in this area; however, I understand that there has been at least one study in the United States in which this method has been under observation in laboratory animals.

Question: How does the rate of absorption via suppository compare to the rate via injection?

Answer: When an absorption promoter was used, I believe that the absorption rate achieved through the use of insulin suppositories was very similar to that obtained through the subcutaneous route.

Question: Do you feel that this alternative treatment method could be viable for use in the control of diabetes?

Answer: To my knowledge, work in this area has been very limited, and has yielded only preliminary results. I would point out, however, that reliance on the chronic use of an absorption promoter theoretically could lead to ulceration of constantly contacted tissue or other harmful effects. We know, too, that the bioavailability--or capacity for absorption--of insulin is quite variable, even when standard injections are used. Until this is investigated further, bioavailability could thus be an obstacle to any widespread effectiveness of insulin suppositories. Finally, there are many toxicological problems that may be encountered in introducing insulin suppositories to the body, problems that could be magnified by the use of this method on a regular or permanent basis.

DIABETES MORTALITY

Question: It is our understanding that diabetes mortality rates differ considerably in the various areas of the United States. For example, the Diabetes Source Book, as revised by the Public Health Service in 1978, indicates that there is a wide discrepancy in terms of geographic areas as to what mortality rates were per 100,000 population.

Why do diabetes mortality rates appear to differ so much in the various areas of the United States?

Answer: Although progress is being made toward identifying determinants of the diabetic state, the reasons underlying geographic and other differences in prevalence and mortality rates for the disease are not completely known. Some of these differences may be due to differences in ascertainment and reporting. In other instances, research is assessing possible local risk factors, including nutrition, obesity, environmental parameters, genetic and immunologic determinants, and socioeconomic variables. Certainly, the possible infectious nature of juvenile diabetes, a possible explanation for geographic disparities in mortality rates, is among the hypotheses that should be further explored. Recognizing the importance of epidemiologic studies in this regard, the NIAMDD is intensifying efforts in this area. For example, recently eight institutes issued a joint Program Announcement soliciting applications for research grants and training awards on the epidemiology of diabetes. Moreover, through the NIAMDD's established National Diabetes Data Group, an intensified effort is being made to collect, analyze, and evaluate diabetes data and to disseminate it in a timely fashion to professional and public groups. The National Diabetes Data Group serves as the principal focus for defining the data needed to address scientific and public health issues in diabetes and for coordinating collection of these data from multiple sources.

Question: Please give us some specific examples of what and how you are coordinating your efforts with the diabetes programs in the Center for Disease Control.

Answer: In the area of diabetes research, the NIH and the Center for Disease Control interact at several levels. For example, representatives from both NIH and CDC serve on the interagency Diabetes Mellitus Coordinating Committee, the National Diabetes Advisory Board, the National Diabetes Information and Education Clearinghouse, and the National Diabetes Data Group. Within the NIH, the National Institute of Arthritis, Metabolism, and Digestive Diseases is strengthening collaborative efforts between its diabetes centers program and the CDC's diabetes control program, particularly when geographic proximity of programs is conducive to extensive interaction. For example, diabetes centers may conduct continuing education programs for individuals within a community whom a CDC program has identified as having instructional needs. Yet another example of cooperation was a workshop on diabetes screening sponsored jointly by the NIAMDD and the CDC in May, 1978.

ENDOCRINE DISORDERS

Question: Dr. Fredrickson and Dr. Whedon, in terms of endocrine disorders, could you give us a picture of what type of interagency programs you have and what the study of the future research directions and funding requirements for endocrine disorders are?

Answer: One program that helps to support the broad field of endocrinology research in a variety of federal and non-federal institutions is the National Pituitary Agency, a contract-supported activity of the National Institute of Arthritis, Metabolism, and Digestive Diseases. Administratively housed at the University of Maryland's Baltimore campus, this agency provides, without charge, human growth hormone and other rare pituitary derivatives to qualified researchers throughout the nation, thus meeting an important need for centralized research resources in endocrinology.

In addition, several institutes at the NIH conduct extensive research in endocrinology and are continuously exchanging information on their progress. For example, the NIAMDD has scheduled inter-Institute Endocrine Grand Rounds at the NIH Clinical Center, and--under the auspices of the Foundation for Advanced Education and the Sciences--the Faculty of the Combined Endocrinology Training Program of the National Institutes of Health presents a lecture series to young investigators.

Yet another coordinated effort to which you refer is a study now under way on "Research Needs in Endocrinology and Metabolic Diseases." This evaluation study, now in its third and final year, is assessing the state-of-the-art in the closely related endocrine and metabolic research areas. As directed by the Senate in a 1977 report (No. 95-283, page 70), the study focuses on NIH-wide supported endocrine research, but the scope extends beyond the NIH to include the entire endocrinology research community. An advisory committee of recognized experts in the various sub-specialties of endocrinology and metabolic diseases is highlighting past research accomplishments, delineating priorities for future research, and evaluating NIH activities and funding levels. The Committee's final report, to be submitted in December, 1979, will be distributed among NIH Institutes and other agencies, as well as to the scientific community, the Congress, and the public at large. It is anticipated that this report will stimulate interest among researchers in the field, promote new directions in research, encourage the interdisciplinary exchange of ideas, and provide scientific administrators with a more effective framework for program management and collaborative efforts.

CYSTIC FIBROSIS

Question: I understand the Cystic Fibrosis Foundation has done a "State of the Art" report on Cystic Fibrosis. What reactions do you have to this report and, in light of their comments and recommendations, what programs are you planning to initiate?

Answer: My reaction to the report, which represents serious and diligent work on the part of a great many individuals, is very favorable. Funded by NIAMDD and NHLBI in response to a Congressional directive, the study identifies many critical needs in research planning and clinical care of CF patients. Over 150 scientists, physicians, allied health professionals, health care administrators, public representatives, government officials and CF patients and their families contributed to the development of this report, which is the result of their collective experiences and insights.

The NIH has and will continue to implement recommendations emanating from this study, within the limits of available resources. Several institutes have developed and issued a coordinated announcement calling for research applications in Cystic Fibrosis. A national conference on Cystic Fibrosis research was held during the first week of March, 1979, to further identify the needs and opportunities for research in Cystic Fibrosis. In addition, a workshop on research resources is planned for this year, and detailed brochures based on the Cystic Fibrosis Report are being prepared for distribution at scientific and professional meetings to let the research community know of the NIH commitment to supporting expanded high quality research in Cystic Fibrosis.

NIAMDD, the NIH component directing the most funds to CF research, would like to increase support of basic studies of the mechanism of exocrine secretion as it relates to cystic fibrosis, encourage development of new or improved diagnostic techniques, such as identification of reliable genetic markers, and promote development of spontaneous or induced models of the disease in experimental animals. Consistent with recommendations of the Report, the NIAMDD is also attempting to reduce the shortage of investigators engaged in CF-related research by providing greater training opportunities in endocrinology, metabolism and other relevant fields. To complement this emphasis on manpower, the Institute is, moreover, considering establishment of a resources program to supply investigators with tissues, cells, and secretory products for CF research. Of course, the extent to which the NIAMDD and other Institutes can be responsive to the recommendations of the Cystic Fibrosis Foundation's Report will be largely dependent on funding and personnel levels in FY 80 and subsequent years.

Question: For the record, would you please provide how much money is being spent on cystic fibrosis in Fiscal 1979 in all the Institutes and what your plans are in Fiscal Year 1980?

Answer: In Fiscal Year 1978, approximately $6.9 million was directed toward cystic fibrosis research by five NIH Institutes: NHLBI, NIAMDD, NIAID, NIGMS, and NICHD. It is estimated that in FY 79 and FY 80 these same Institutes will support CF research at funding levels of $9.1 and $9.3 million, respectively.

Question: Dr. Fredrickson, are you satisfied with the level of cooperation among the various Institutes relating to cystic fibrosis research?

Answer: Yes. Cystic Fibrosis (CF) is an inherited disease, presumably caused by an "error of metabolism," that affects most of the major organ systems of the body in severely affected individuals. Its widespread manifestations make it of interest to no less than five of the Institutes and Divisions of NIH. These seven cooperate in the planning and funding of research through the NIH CF Coordinating Committee. They have, for example, issued a joint program announcement requesting the submission of project proposals relevant to Cystic Fibrosis. Two institutes cooperated to sponsor the "State of the Art" study referred to above. Three have cooperated to underwrite a recently concluded scientific

conference to review research frontiers, to bring together researchers who have long experience with CF and others concerned with the more basic sciences, and to plan new approaches to the puzzle presented by CF. To the best of my knowledge, no promising research lead in CF is being neglected as a result of "falling through the cracks" between individual Institutes' programs. On the other hand, I know of no wasteful duplication of effort stemming from the funding of identical research projects by separate Institutes.

Question: Dr. Fredrickson, what impact do you think the tight Fiscal Year 1980 budget will have on this important area?

Answer: While the proposed budget will certainly permit continued NIH efforts in CF research, FY 80 funding limitations will no doubt affect the number and magnitude of CF-related activities that can be supported.

National Institute of Neurological and Communicative Disorders and Stroke

STATEMENT OF DONALD B. TOWER, DIRECTOR

ACCOMPANIED BY:

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WILLIAM B. MATTHEWS, JR., BUDGET OFFICER, NATIONAL INSTITUTE OF NEUROLOGICAL AND COMMUNICATIVE DISORDERS AND STROKE, NIH
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WILFORD J. FORBUSH, DEPUTY ASSISTANT SECRETARY, BUDGET, DHEW

1979 APPROPRIATION AND 1980 BUDGET REQUEST

Senator Schweiker. Our next witness will be Dr. Donald Tower, who is director of the Neurology Institute. Your budget request, Dr. Tower, is $212,322,000, just about exactly the same as was provided in fiscal year 1979.

PREPARED STATEMENT

Dr. Tower, in accordance with our procedure, we will put your complete statement in the record, and we will be glad to have you summarize highlights that you would like to mention at this point.

[The statement follows:]

STATEMENT OF DONALD B. TOWER

Mr. Chairman and Members of the Committee:

To the extent that neurological and communicative disorders "de-encephalize" man, they also de-humanize him as artisan, as recorder of history, and as architect of his destiny. These words underscore the fact that the brain is the most complex biological system in the universe. Brain research differs from most other aspects of biomedical research since it focusses on the neurological basis of human nature. To know one's self is in essence to know one's brain--to probe the central issues of mind, consciousness and intelligence. As one of our consultants has put it: Brain, understanding itself, remains man's supreme challenge.

To meet this challenge, the NINCDS National Advisory Council charged the NINCDS to develop during FY 1978 long-range strategies for research on the nervous system and its disorders. Position papers and recommended strategies have been submitted from seven panels and two task forces of outside experts, as well as from a public forum held with representatives from most of the voluntary health agencies concerned with the mission of the NINCDS. The NINCDS National Advisory Council has now approved these reports and the summary volume which synthesizes these various inputs and identifies research goals and the requisite resources. Advisory Council and Institute program staff together believe that this set of guidelines or blueprint for research strategies will serve as a basis for effective planning of future research directions and resource allocations.

At almost the midpoint in FY 1979 we can provide a reasonably good estimate for NINCDS of this year's research progress. A significantly greater number of research grant applications have been submitted to the NINCDS in FY 1979 . Moreover, the scientific merit of approved grant applications is increasing, as indicated by more applications recommended for priority scores in the 100-to-200 range. For FY 1979 the NINCDS expects to be able to fund some 50 to 55% of the grant applications recommended for approval, through a priority score of approximately 225. Of the $34 million increase appropriated for the NINCDS in FY 1979, an estimated 78% provides for funding of competing research grants, and another 12% provides additional research initiatives and resources for scientists in our intramural laboratories at Bethesda. Approximately 18% of the appropriation increase is being devoted to the implementation of recommendations made by the National Epilepsy and National Huntington's Disease Commissions.

Basic and clinical investigators are amongst the most important ingredients for a successful research mission. In FY 1978 the NINCDS supported the training of some 55 pre-doctoral fellows and 400 post-doctoral fellows (two-thirds on individual NRSA fellowships; the rest supported under 45 institutional awards) at a total funding of $7.3 million. In addition some $6 million from grant funds is currently devoted to the 5-year research career development awards (RCDA) and teacher-investigator development awards (TIDA). To complement the RCDA program aimed primarily at basic research needs, the TIDA's are awarded primarily to physicians to recruit and prepare them for future careers in clinical research and teaching in neurological and communicative disciplines. We attach particular importance to these training programs, because today neuroscience has become a way of thinking about the nervous system. It is no longer a hybridization of traditional disciplines but rather a conceptual schema for unifying multidisciplinary studies of the nervous system and its disorders.

Now let me mention briefly some highlights of current research progress and important future prospects. The NINCDS continues to explore new approaches to the basic problems of access to and transfer of research information. Scientists in our Communicative Disorders Program have been working for two years with consultants and with staff of the National Library of Medicine to utilize the MEDLARS on-line retrieval services to meet the information needs of clinicians and scientists in the communicative sciences and disorders. As a result, a number of scientific journals have been added

to the lists being indexed for MEDLARS; specific indexing terms and synonyms for existing terms have been added; and a user's manual and a Thesaurus of MEDLARS vocabulary have been prepared. This project is being watched with great interest; such an approach may be preferable to the current information services now supported for other areas of NINCDS responsibility.

By July of this year, the NINCDS will have a complete turnover of the five directors of its extramural programs. Recruitments and selection of replacements are complete for three; and search committees are in operation for replacement of the other two. Skilled and devoted staff in each of those programs have ensured continuity of research efforts and smooth transitions. We have made several other key appointments: after a 3-year search, recruitment of a multiple sclerosis (MS) expert to take charge of the MS and related research sub-programs; recruitment of an expert in Huntington's disease and other neurogenetic disorders to oversee these areas of research; and after a 4-year search, the selection of a new chief of the intramural surgical neurology branch.

A brief cataloguing of research happenings over the past year indicates the diversity of NINCDS research programs. Accession of patients is well under way into the multicenter, randomized clinical evaluation of the neurosurgical procedure joining a scalp artery to a brain artery (the so-called extracranial-to-intracranial arterial anastomosis) for the prevention of transient ischemic attacks (so-called little strokes) and subsequent frank stroke. More than 30 centers in the U.S., Canada, Europe and Japan are collaborating in this study. Another study is under way to evaluate the efficacy of high versus the usual low doses of steroid therapy in the management of acute spinal cord injuries. Seven centers are collaborating in this double-blind prospective study. Aggressive treatment of acute injuries to the nervous system takes on greater significance from the report by one of the NINCDS-supported head injury clinical research centers that aggressive acute treatment reduces mortality by more than 40%. The NINCDS epilepsy sub-program supported some 32 clinical trials of new or potential anticonvulsant drugs during the past year. As one result of such studies, epilepsy benefitted by the approval in 1978 of sodium valproate for marketing as the latest addition to the armamentarium of anticonvulsant drugs.

Research on central nervous system regeneration is now a flourishing sub-program, with close to $7 million of funding. Despite media reports to the contrary, careful evaluations of Soviet practice and the condition of American paraplegics on their return from Soviet clinics provide no evidence of any therapeutic breakthroughs in this field in the Soviet Union. An NINCDS-supported careful duplication of the Soviet reported enzyme treatment of animals with experimentally transected spinal cords has failed to confirm any restoration of function as Soviet scientists had claimed. Several other independent attempts to duplicate the Soviet findings also failed. More promising are several studies by American investigators indicating that in experimental animals the use of homologous (same animal) grafts or allografts (same species matched for low antigenicity) of peripheral nerve may be able to provide a milieu in nerve and perhaps in spinal cord for the cut fibers to regenerate across the gap.

Developments of neural prostheses for paralyzed and disabled patients continue. An NINCDS contractor is currently conducting a 6-month test in dogs of a prosthesis for the paralyzed urinary bladder; if all goes well, it should be ready for human trials later this year. Also prostheses with multiple electrodes for sensori-neural deafness have been designed and tested, with indications that crude discriminations of pitch may thus be provided to improve the auditory alerting which such prostheses provide. Perhaps the most intriguing studies are being conducted by NINCDS intramural scientists who have designed a variety of special stimulating and recording electrodes for the long-term study of motor (muscle) activity in intact, active and free-ranging experimental animals. The aim is to understand the motor organization of the nervous system from motor units in specific muscles to spinal cord and to the brain. Such research is particularly relevant to understanding a number of motor disorders like amyotrophic lateral sclerosis (ALS), the hereditary ataxias, and muscular dystrophy.

Investigation of the specific receptors for each of the growing array of chemical transmitters of nerve impulses is one of the exciting areas of current neuroscientific research. For the dopamine transmitter system (which is impaired in Parkinson's disease), it is now clear that there are two biochemically distinct types of dopamine receptors in the brain, and at least five sub-types can be distinguished by neuropharmacological (drug effect) testing. The diversity of actions of the peptide (small protein-like) transmitter molecules continues to be impressive. A number of studies distinguish neurohormonal, neurotransmitter, and neuromodulatory effects by the same peptide depending on the nature of the neuronal receptor. The modulatory actions are especially important as a means of fine control of synaptic (transmission) efficacy at specific synapses in the brain and spinal cord. The opioid or endorphin class of peptides is clearly involved in central pain mechanisms and behavioral and hormonal aspects of brain function. Now we are confronted by a whole new system of receptors on nerve cells--receptors to the benzodiazepine class of drugs (such as Valium), and evidence that the natural or endogenous chemicals for which these receptors are intended are purines (one of the building blocks of the nucleic acids, more familiar as genetic materials like DNA and RNA). No doubt other systems remain to be discovered. Thus, we see in this variety and diversity of transmitter, hormonal and modulatory agents the complexity and sophistication of the brain's biochemical circuitry, essential to its integrative, behavioral and intellectual functions.

Another very active research area is concerned with neuroimmunological and neuroviral studies, with special relevance to multiple sclerosis (MS) and related disorders. MS is characterized by spotty demyelination (loss of the fatty myelin sheath insulation around nerve fibers), and study of specific myelin-associated proteins liberated by the myelin breakdown is proving especially informative. NINCDS scientists have developed highly sensitive immunochemical tests for two of these proteins. In MS involved areas of brain, they find that one protein exhibits earlier and more widespread increase than would be expected from previous microscopic studies. Furthermore the new observations indicate the occurrence of re-myelination or repair in some areas. Because MS appears to be an auto-immune disorder (one in which the body becomes sensitized to its own tissues), there is special interest in the suppressor lymphocyte cells of the immune system which are thought to normally prevent development of autoimmune disorders. Several studies by NINCDS scientists suggest that the suppressor cell response is abnormal in MS. Thus, if tolerance to one's own tissue cells is maintained by suppressor cells, then if the suppressor cells lose their responsiveness (perhaps because of a specific viral insult), an autoimmune disease like MS could ensue.

Finally, a glimpse of the future. This year the NINCDS is embarking on a modest special initiative to exploit an intriguing new research technique, postiron emission transverse tomography (PETT). What CAT brain scans have done for our ability to visualize the anatomy and structural pathology of the intact living brain, PETT promises to do for the metabolism and function of the intact living brain in situ. We at NINCDS view this as an exciting research technique especially, perhaps uniquely, applicable to the solution of nervous system problems. To be able at last to examine functional changes in the intact human brain during complex integrated activity such as speaking, hearing, seeing or mental processing; to be able to evaluate changes in human brain metabolism before, during and after an epileptic seizure or a transient ischemic attack (a little stroke); to be able to ascertain without intervention the extent and malignancy of a brain tumor and its response to chemotherapy; to evaluate neuronal integrity in stroke or head injury; to probe for biochemical abnormalitites in Huntington's disease, ALS, or Alzheimer's disease; to be able to examine an MS plaque in formation; to be able to study central processing in brains of autistic children; to be able to do all these and more literally boggles the mind. None of the answers will come easily or immediately. But the potential payoffs are so great that the NINCDS believes this research initiative to be imperative.

In conclusion, Mr. Chairman, the budget request for the National Institute of Neurological and Communicative Disorders and Stroke for 1980 is $212,322,000. I shall be pleased to supply additional information as desired for the record and to answer any questions. Thank you.

LONG-RANGE STRATEGY FOR RESEARCH

Dr. TOWER. Senator Schweiker, I would like to make a few points that are given more detail in my opening statement. First of all, we have just about completed an exercise which our advisory council charged us with starting last year, to develop long-range research strategy for the future.

I have brought with me what is essentially a final draft, summarizing the deliberations of seven panels of outside experts, two task forces, a public forum, our own program staff, and our advisory council, to ascertain where we are, where we should be going, what resources it will take, and to give us a basis for developing some of those priorities and strategies that you were discussing a few minutes ago with Dr. Fredrickson.

I don't know that this is the whole answer to your question, but I think it gives us a much better basis for dealing with some of the concerns that you raised about relative priorities.

Senator SCHWEIKER. I think so, too, Doctor. I know when I had a rather lengthy in-depth visit with you folks, we went over all these things, and this struck me as a very sound approach to try to begin to choose priorities, and also reduce to writing some of the conflicting pressures, and also some of the competing priorities that you have in your Institute, too.

So, I did have a chance, and you gave me one of the draft copies at that point, to leaf through it. I was impressed with it then, and I think it does serve a very valuable purpose to help assist us in looking at research on a more objective basis.

Go ahead.

Dr. TOWER. It is our plan to work not only with our own people, and with the advisory groups on the outside, but with the Congress, to try and utilize this as a basis for dealing with some of these very difficult questions which you have been discussing here with all of us.

APPROPRIATION INCREASE

The second point I would like to make is that we have taken the increase in the appropriation that the Congress voted us for fiscal 1979, approximately $34 million in our case, for funding research grants. We funded approximately 50 to 55 percent of the approved competing grants this year, and 78 percent of the money that you gave us went to these competing research grants, and another 12 percent went to our intramural research program so that approximately 90 percent of the money that was voted went for research.

Within that, about one-fifth of the money went for beginning the implementation of recommendations of the National Epilepsy and Huntington's Disease Commissions.

I would like to mention in passing an effort we have underway in collaboration with the National Library of Medicine, and our communicative disorders program for a better procedure for providing transfer between what is in the literature and needs of the scientist on the outside. We have brought this to the field testing phase at this time, to make it possible for scientists and researchers to interface directly with the MEDLARS data bases and the MEDLINE system of the National Library of Medicine. We hope that this will

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prove a much more efficient way of providing custom tailored information needs for the researcher.

STAFF RECRUITMENT

As you may know, we have had a considerable turnover in our extramural directors. All five of them will have left by the end of July.

Senator SCHWEIKER. Why is that, salary?

Dr. TOWER. A number of different reasons, sir. Salary probably the least, it might surprise you. But a number of different reasons have come up, retirement, other jobs, and so forth.

The recruitment is a little more difficult. I think we have recruited three out of the five, the last one being the director of the communicative disorders program, who is coming to us, according to his letter, but we have a salary problem, and we have the other problems that you are aware of in the senior executive service, the ethics problems, and so forth, still to get over. But I hope we shall be able to deal with that.

I'm happy to report that we were able to recruit a first-class neurosurgeon into our intramural program to lead our surgical neurology branch. This has been a real feather in the cap of our program.

We have also finally been able, after 4 years of searching, to be able to bring in a head of the extramural multiple sclerosis branch.

That was one of the recommendations of the Multiple Sclerosis Commission, which was still outstanding, and I am happy that we can finally write that one off as a success.

We also appointed a senior scientist for the genetics area, which will help to deal with the recommendation of the Huntington's Disease Commission.

CLINICAL TRIALS

We have a number of clinical trials underway, which I think are particularly important. We've recruited 30 centers into our collaborative randomized trials for the evaluation of the surgical procedures which connect a scalp artery to a brain artery to provide increased blood flow into the brain. If this is indeed a successful procedure, and that is what the evaluation is designed to find out, we will make another inroad into the whole stroke problem, because the operation is designed to get around some of the narrowing and insufficient flow of the normal arterial supply to the brain.

We are looking into better methods of treating spinal cord injuries, and we have seven centers in that study. Here we are getting into the area of what I would have to call aggressive treatment of injury to the nervous system. It appears from preliminary results that this is going to reduce markedly the morbidity and mortality in these injuries.

I think, therefore, these trials are extraordinarily important evaluations.

In the case of epilepsy, we've conducted 32 clinical trials for evaluating new drugs this year, and we are happy to report that after our hearings last year, sodium valproate, the new drug that we discussed last year, finally did get into the marketplace.

REGENERATION RESEARCH

We have a very successful program going on in research on the regeneration of the central nervous system, particularly after spinal cord injuries. We are now up to $7 million from zero dollars just a few years ago, and I think this is one of our most flourishing areas.

I would like to say in this regard that we have looked very carefully at the claims that have been made for Soviet advances in this area. You have read about them in the newspaper, paraplegics going to Leningrad for enzyme therapy and all that sort of thing. Unfortunately, the claims appear to be groundless.

We have evaluations of the paraplegics who have come back from the Soviet Union. We have had reports from three different groups, including one from the Veterans Administration, who visited the Soviet Union, and looked into these matters. We also have the attempted reproductions of the experimental work which was reported from the Soviet Union, precisely repeated in this country by our scientists, and none of these studies, unfortunately, have paid off.

So that I think we must accept the fact that these Soviet claims are without foundation.

Senator SCHWEIKER. Doctor, I don't disagree with that. But if that is the case, how do you account for the widespread media focus that seems to raise expectations and promises in this area?

Dr. TOWER. I'm afraid, Senator, that these are misunderstandings, misquotations and that sort of thing. The media, I think, have not always asked all the questions that they should have.

Senator SCHWEIKER. I'll buy that.

Dr. TOWER. Before putting the reports out.

Senator SCHWEIKER. You made your point there.

Dr. TOWER. We have prepared a very careful report of what the status of this situation is, which we will be glad to submit to you for the record.

Senator SCHWEIKER. I think we should have it for the record. I think it does raise false hopes and expectations.

Dr. TOWER. That is exactly the problem. I would like to point out for the record that the two organizations which deal with paraplegics have provided a great deal of information that goes into this record.

Senator SCHWEIKER. The staff asked me to ask you how long the report is.

Dr. TOWER. It's about two pages.

Senator SCHWEIKER. You will pass the test around here.

[The information follows:]

A STATUS REPORT ON RUSSIAN ENZYME THERAPY AND HYPERBARIA

There have been reports in the scientific literature and in the public press during the past few years about new therapies for the restitution of function following transection of the spinal cord. The most recent publication originates from the Soviet Union where Dr. Levon Matinian, a neuroscientist, reported that the use of emzymes immediately following transection resulted in regeneration of the spinal cord in rats with subsequent restoration of muscle and organ function. These reports were followed by anecdotal accounts of the success of enzyme therapy in human paraplegics under the care of Dr. Veniamin Ugriumov, Director of the Leningrad Research Institute of Neurosurgery.

In May–June 1976, the National Institute of Neurological and Communicative Disorders and Stroke—National Institutes of Health invited Dr. Matinian and Dr. Ugriumov to the United States to learn more about their methods and results. Although Dr. Matinian's report on his experiments in the rat were considered provocative, his methodology and data raised questions about the interpretation of his results. In order to test the validity of Dr. Matinian's findings, identical experiments have been repeated in the United States. The results of these experiments are now available. The U.S. investigators report that "no evidence was found that enzyme treatment significantly reduced scar locomotion in spinal rats." They further state that "the report of spinal recovery following transection was probably due to incompleteness of the transection rather than to enzyme treatment." Thus, serious doubt now exists about the validity of Dr. Matinian's findings and about their applicability to the treatment of spinal injury in the human.

Dr. Ugriumov did not present any scientific data but spoke in broad terms of his general approach to therapy. The surgical, medical and rehabilitative methods used at the Leningrad Institute are the same as those used in the United States. He reported that enzyme therapy had been used in a few patients as part of the total treatment program, but he stated that he had no evidence that they had any beneficial effect. The only "special approaches" stressed by Dr. Ugriumov were immediate surgical-medical therapy after injury and intense physiotherapy supported by psychological reinforcement. In recent years, a number of paraplegics from the United States have gone to the Leningrad Institute for "enzyme therapy."

The staff of the NINCDS did not examine any of these persons either before or after their return from the Soviet Union. However, reports from U.S. physicians in charge of their treatment program and newspaper articles indicate quite clearly that they all remain paraplegic and that any "improvements" are clearly those attributable to intensive physiotherapy and psychological support. There is no indication that enzyme therapy is of any benefit nor that Soviet physicians have any medical, surgical or rehabilitative methods which are not being used regularly in U.S. centers. Although enzyme therapy and hyperbaric oxygenation is being used on occasion at the Leningrad Institute, there are no clinical or research reports of their usefulness individually or in combination. Also, we have been informed by clinical scientists and physicians who have recently returned from the Soviet Union that physicians in the Soviet Union do not support the use of enzymes to "cure" paraplegia.

It should be pointed out that the research program of the NINCDS–NIH is the largest coordinated research effort in the world on the therapy of acute spinal cord injury and regeneration of the central nervous system. This effort is complemented by the research and clinical service programs of the Veterans' Administration, the Rehabilitation Services Administration, and the emergency medical services program of the Health Services Administration. Every promising lead to prevent paraplegia and to restore function to the paraplegic is being vigorously pursued. Periodic research workshops are sponsored regularly in which U.S. and foreign investigators share results and new leads. It would be highly unlikely for any "breakthough" to occur and the NINCDS–NIH be uninformed. To date, there has been steady progress but no breakthroughs. There is no indication that enzyme therapy or hyperbaric oxygenation is of any value in the treatment of paraplegics, either at the time of injury or later.

Research offers substantial promise that paraplegia may be prevented. Whether is can be cured is as yet unknown. Many false leads have been pursued and probably will continue to be pursued in the future. However, hints of miraculous cures are cruel jokes on persons who need to receive the best treatment available and then get on with their lives. Hopefully the paraplegia community through their national organizations will continue to keep itself informed of the facts as they are presently known and of progress in research. I am certain that neither Dr. Matinian nor Dr. Ugriumov are offering cures; however, Dr. Matinian's basic research and Dr. Ugriumov's clinical explorations are being badly misinterpreted and falsely exploited.

Dr. TOWER. I would like to emphasize that we think some of the research that is going on in this country is much more likely to pay off in the long run. I refer to some of the experimental grafting procedures with nerves, which appear to provide a milieu over which the cut ends or the damaged ends of spinal cord fibers may be able to regrow.

It is too early to say for sure, but we believe that this may have much more promise than some of the other procedures that have been proposed in the past.

BASIC RESEARCH

I will mention very briefly the exciting areas of receptors and transmitters in the central nervous system. We are learning a lot about this in the research that we are supporting. There are so many systems coming to the fore now that we can quite understand how the human brain can be as complex and versatile and sophisticated as it is.

Many of the payoffs in this kind of research will come in important areas, such as pain, behavior, and the whole question of how the input-output functions of the central nervous system are modulated.

In the area of infectious and immunological diseases of the nervous system, multiple sclerosis is perhaps the best example of the complexities in the disorder area, but, again, we are learning a great deal by the research going on. Here, I would refer particularly to the isolation and utilization by immunochemical means of specific proteins from the myelin sheath which insulates nerves and is the site where multiple sclerosis lesions occur.

This type of research has allowed us to get a much better idea of what is going on in the multiple sclerosis process, and to even be able to demonstrate now that repair does start to occur.

In other words, it is not a one-way process. If we can learn how to stimulate that repair and perpetuate it, we may eventually be able to heal the lesions of multiple sclerosis. Then we are looking at the immune system, because multiple sclerosis is an autoimmune disease. The body begins to react to its own tissues.

We are beginning to learn about the suppressor lymphocytes, which normally prevent such reactions and appear to be abnormal in mutiple sclerosis. If we can learn more about that, we might very well be able to approach the problem from that side.

POSITRON EMISSION TRANSVERSE TOMOGRAPHY

Finally, I would like to mention one of the most exciting developments that has occurred in the last year, and represents a special initiative, which, regardless of how deeply you cut us, we intend to initiate this coming year.

Senator SCHWEIKER. I feel a sense of priority there.

Dr. TOWER. That is right, Mr. Chairman.

Senator SCHWEIKER. That would stand a 5-percent cut.

Dr. TOWER. This is what is called officially positron emission transverse tomography, or in short, PETT.

Now, you are familiar with the brain scans that have been in use over the last decade or so. What they have done for the anatomy, and the pathology of the central nervous system, PETT will do for the metabolism and function of the central nervous system.

We believe that this is an exciting research technique which is perhaps specially or even uniquely applicable to solutions of nervous system problems. To be able at last to examine functional changes in the intact living brain during complex integrative activ-

ity, such as speaking, hearing, seeing, or mental processing; to be able to evaluate changes in human brain metabolism, before, during, and after an epileptic seizure, or a stroke; to be able to ascertain without intervention the extent and magnitude of a brain tumor and its response to chemotherapy; to evaluate head injury, to probe for biochemical abnormalities in Huntington's disease or Alzheimer's disease, to be able to examine multiple sclerosis lesions information; to be able to study sensory processes in the brains of autistic children; to be able to do all of these and more, literally boggles the mind.

That is what this technique promises to do for us. None of these answers will come easily. They will require a great deal of experimental work. We believe the potential payoffs are so great, that this research is imperative.

Thank you, Mr. Chairman.

Senator SCHWEIKER. I know you mentioned this during my visit, and I was impressed with the possibilities here, so I'll continue to be impressed. I'll join you in making the last stand in cuts on this item, Dr. Tower.

Could you put there in layman's terms, what this would possibly do, in terms of how it functions, or will hopefully function?

Dr. TOWER. Well, I brought a——

Senator SCHWEIKER. Just happened to have it.

Dr. TOWER. I brought an illustration of the model T version with me. This is a technique which is now used by Swedish and Danish investigators, where you can only look at the surface of the brain, and the different colors represent how much blood is flowing through it.

By this technique, they have been able to show what happens when you count out loud, or when you count mentally, and you can see different changes in the amount of flow that goes to different areas in the brain.

As I say, this is the model T. What we are proposing with the PETT technique, and it has already been tried out to the extent that we know it is potentially possible to do it, is to look at the whole brain in three dimensions, not only to look at blood flow, but to look at how sugar is metabolized be cells, that even gets us into problems with diabetes.

Senator SCHWEIKER. I knew you would get that in there. You are doing all right.

Dr. TOWER. We can look at what happens during the development of a stroke, and when the brain begins to recover from the stroke, and what our therapy may or may not be doing to it.

We can look at what is happening in a multiple sclerosis lesion, and whether some of the things that are now being proposed as experimental therapies indeed are managing to repair the damage.

There are an unlimited number of things that we can look at. And what we are proposing is to fund a limited number of centers that have the technology and manpower to be able to utilize this technique, and to pool our resources in such a way that we will be able to cover as much of the research potential as possible without having umpteen centers out there, and to probe in a way which we hope will be the most responsive way to develop appropriate research.

I do not think that this is going to be a diagnostic technique, at least at this stage. It is much too expensive, much too complicated. But for research, it is going to allow us to do extraordinary things. Senator, I'm a biochemist, and in terms of my own research, and from what I can learn about this technique, I can see solutions to problems where there just weren't any solutions before this technique came along.

Senator SCHWEIKER. When you look at a function of the brain, like you are describing, your three-dimension as opposed to two, you mentioned blood flow.

Are there other functions you see?

Dr. TOWER. Yes, sir.

For example, we have a whole variety of receptors for the chemical transmitters that allow nerves to communicate with each other, and we have a certain number of drugs which will affect the way in which these receptors function.

The best known is L-dopa for treating Parkinson's disease. That is a drug that hits the receptors. We also can make antibodies to the receptors, which will show us where they are.

With this PETT technique, we can see what happens to those systems in the living, intact, human brain.

Senator SCHWEIKER. What I don't quite understand is what happens in what functional respect? You say blood flow is one. What other functional respects would it refer to?

Dr. TOWER. As you are speaking and getting more frustrated with not getting the answer from me, I can show you what is happening in those particular areas of your brain.

Dr. FREDRICKSON. Utilizing energy.

Dr. TOWER. We can look at energy utilization.

Senator SCHWEIKER. Chemical reactions per se or just the end products?

Dr. TOWER. Chemical reaction per se. That is something which will take ingenuity, and a lot of experimental study, but the possibilities are there, and one of these days we will come back and tell you about it.

We already have enough data to know that this will work.

Senator SCHWEIKER. You are saying that the technology of it is known.

Dr. TOWER. Yes, sir.

Senator SCHWEIKER. The application or meaning or implication of it is not known.

Dr. TOWER. Yes, sir.

IMPLEMENTATION OF COMMISSION RECOMMENDATIONS

Senator SCHWEIKER. Dr. Tower, you did touch on part of this, but I would like to ask you for the record. Please review for the committee what your plans are in fiscal 1980 with a level budget, how you plan to implement the Huntington's Disease Commission's recommendations and those of the Epilepsy Commission.

Dr. TOWER. Senator, we will not be able to implement any of the very large recommendations of the Epilepsy Commission, for example, additional comprehensive centers, each of which runs somewhere close $1 million apiece.

Obviously, this will not be possible. We have five going already, and we will be able to maintain those.

But we will not be able to implement any more.

We expect to be able to implement, even with a reduced budget, at least one of the centers without walls that the Huntington's Disease Commission recommended.

We have already prepared the request for grant application that will go out shortly, and we expect to fund that in fiscal 1980.

Senator SCHWEIKER. For the record, then, would you explain the funding for 1980 for the Huntington's and Epilepsy Commissions.

Dr. TOWER. We've already submitted a report to the committee on that.

Senator SCHWEIKER. In last year's committee report, the committee directed you to put a great deal of new emphasis on communicative disorders in your Institute.

I wonder if you would outline for us what you have done to implement this.

Dr. TOWER. The first thing we have done is to try to get a new director in the program. That I think we are successfully doing.

But we have, I think, developed some very good new initiatives in the communicative disorders, and either maintained or increased those which were ongoing.

The appropriation portion that goes to the communicative disorders has been increased by a considerable figure over 1978.

The particular number—I'll dig it out here—in 1978 was approximately $29 million, and this year we were spending $34 million.

That is roughly a 17-percent increase in the 1 year. The number of new grants funded has gone up significantly, so that the research effort from investigator-initiated grants has substantially increased. In some of the areas where there is a relative paucity of investigators out there, we have increased our contract program, particularly in the speech and language area. I think that these efforts are beginning to pay off, both in terms of the new knowledge acquired and the stimulation of the community to go into research and to submit grants in these areas.

I think perhaps the best answer to your question, Senator Schweiker, is that we have seen this year, in fiscal 1979, an increase in the number of grants, a significant increase in the number of grants submitted in the communicative disorders area, and a very significant increase in the priority scores that these grants have commanded.

In other words, the scientific quality of these grants has improved immensely.

So the share of the budget that the communicative disorders program is commanding is going up as a result of that.

HEARING RESEARCH

Senator SCHWEIKER. Dr. Tower, during my visit there with you and with the intramural research function of communicative disorders, I became aware of an exciting program in the field of hearing research with the development of our ability to grow mouse inner-ear cells in the laboratory.

I wonder if you would explain for the record why this is important, and what you will be doing in the future as to this research?

Dr. TOWER. This is an extraordinarly exciting technique. It utilizes the embryonic mouse ear, and the ability to culture the inner ear cochlear tissue in organ culture.

This was developed by one of our grantees in New York, who has demonstrated that not only is this feasible, but it is something that almost any experienced investigator in that research area can learn to do.

Now what this promises for us is, first of all, to let us understand how the organ concerned with transduction of sounds into coded nerve signals, which is what the inner ear does, how that organ develops, and how various influences during the development period, pregnancy, if you will, can alter normal development, how we can account for the many cases of so-called congenital deafness that we see.

Some of these are genetically determined. The genes are defective as they are passed on from one generation to another. But many of them are not genetically determined and, therefore, must be due to environmental changes in the developing inner ear during the time of gestation.

Therefore, this technique will allow us eventually to prevent a great many of the cases of children who are now born congenitally deaf.

In addition to that, I think it will help us to understand a great deal about the sensitivity of the inner ear to the various agents that may impinge upon it, not only infectious agents, which we know are important, things like German measles and influenza, but any of the toxic agents, radiation agents, and that sort of thing which affect all embryonic growing tissues, and some of which are very specific for the ear.

This provides us with a very extraordinarily useful preparation in addition, because as it matures, we have essentially an organ in isolation, which one can study to deal with the very complicated question of how the mechanical sound waves are accepted by the hair cells and transduced into nerve impulses.

Senator SCHWEIKER. Is this the best prototype of any cells that we had from the animal kingdom?

Dr. TOWER. This is the only one, for the inner year.

Senator SCHWEIKER. The only one?

Dr. TOWER. Yes, sir. In addition to that, there is one advantage of the mouse for this work, because there is a great repository of mutant strains of mice with all sorts of genetic differences and characteristics, which are well-documented and well understood, even to the immunological areas and other areas, so that one can draw upon a library of variations in order to do this type of research.

Senator SCHWEIKER. What will the 1980 budget do to this program?

Dr. TOWER. It will defer it, sir.

Senator SCHWEIKER. I was afraid of that.

We will make a last stand on this project.

I think this is a breakthrough, and I think the intramural lab is to be congratulated, as well as your Institute in pursuing this, and

we certainly ought to be able to fund something as fundamental as hearing. I just want to say you certainly have my support.

STAFF RECRUITMENT PROBLEMS

Have you run into difficulties in recruiting a program staff?

Dr. TOWER. Yes, sir, we have.

Senator SCHWEIKER. We talked about this earlier, I know. Maybe you want to elaborate a little bit.

Senator TOWER. It took us 4 years to recruit a neurosurgeon to head our neurology branch. The main stumbling block was salary.

We already have questions being raised with regard to salary by some of the people we are recruiting from the outside for vacancies.

I think, in addition to that, we are going to encounter some problems that are imposed by the senior executive service, and the Government ethics provisions, which are now before us.

Those people who may plan after retirement from the Government to go into deanships and things like that are having second thoughts about some of the restrictions that the Ethics Act has imposed.

There are many uncertainties with regard to the senior executive levels. It is very hard to take somebody from the outside making $80,000 or $90,000 and not be able to tell them what salary we can offer them, beyond the $47,500 ceiling that we have at the moment.

We don't know what the provisions of the senior executive service will be.

Senator SCHWEIKER. When is that due out?

Dr. TOWER. The decision for current employees in the Government will have to be made by July 11, which I believe is the cut-off date. But those coming from outside must go into the executive service.

We are not sure what the remuneration possibilities are. There are bonus provisions, but we don't know how they are going to be applied.

Senator SCHWEIKER. Who is formulating that now?

Dr. TOWER. The Department has those under review. We don't know when the decisions will be made.

In addition to that, there is the separate legislation which allows a bonus for all the physicians in the civil service.

We don't know that that is legally applicable to those in the senior executive service.

We believe not.

Senator SCHWEIKER. You have recently filled, as you mentioned, I believe, a position on the communicative disorders program.

Dr. TOWER. Yes, sir. We have a letter of acceptance. He is not on board yet.

Senator SCHWEIKER. He is coming on board in the fall of this year?

Dr. TOWER. Yes, sir.

Senator SCHWEIKER. How long has that position been vacant?

Dr. TOWER. That position has been vacant precisely a year at this point.

Senator SCHWEIKER. You say you have a letter, and he won't come until when?

Dr. TOWER. September.

Senator SCHWEIKER. Why is that time frame so long?

Dr. TOWER. Two factors. His personal factors, the commitments he has, selling his house, and so forth.

But more important, the time it takes to process the paperwork through the system.

The Civil Service Commission must approve the position and the grade before they even consider the individual.

That is one whole process in itself.

And second, once you have selected the individual, they have to re-examine to see whether he is qualified for that position.

In our experience, that has taken a minimum of 3 months.

Senator SCHWEIKER. How many months?

Dr. TOWER. A minimum of 3 months and in most cases more like 4 to 6 months.

Senator SCHWEIKER. Who does this come under?

Dr. TOWER. Partly the Department and partly the Civil Service Commission.

Senator SCHWEIKER. Who is from the Department here?

OK. You volunteered. Why do we do that?

Ms. WORMSER. That is the standard personnel procedure. It goes on throughout the Government. The Department is not an exception.

Senator SCHWEIKER. It takes that long throughout the Government. That seems unduly long.

Ms. WORMSER. I can't dispute that, but that is a pretty general timetable. The Civil Service Commission has to verify that the credentials of the candidate meet those of the position.

Mr. SCHWARTZ. I would like to make a comment about this. The Civil Service Reform Act took this into consideration, and I'm very optimistic that this new Office of Personnel Management will delegate a great deal of authority to the Department.

Senator SCHWEIKER. In this area?

Mr. SCHWARTZ. Yes, sir.

Senator SCHWEIKER. Specifically on paperwork?

Mr. SCHWARTZ. That is correct. It remains to be seen. What I'm talking about is the rhetoric and discussion, that so far has given me some optimism that this will be approved.

Senator SCHWEIKER. I think maybe the the committee ought to direct an inquiry to both the civil service and the Department on this matter. I think it's scandalous to have that kind of time frame.

A joint letter ought to go from the chairman and me to find out what is going on.

Dr. TOWER. May I say, Senator Schweiker——

Senator SCHWEIKER. You will sign the letter, Dr. Tower.

Dr. TOWER. No, sir. It makes recruiting extremely difficult, because you've got somebody hanging on the line for 6 months.

Senator SCHWEIKER. I think we will use your illustration of the time frame. I think it is really scandalous.

Dr. TOWER. We've got plenty of examples.

Senator SCHWEIKER. We will use this one. I can understand with the other constraints we place on people, in terms of pay, ethics

and everything else, but we don't need a lot or redtape hassle delaying the hiring of essential personnel.

So we will send a joint letter, I think, on that.

DRUG DEVELOPMENT

Doctor, I do have one more question:

How do you work with the private sector, the pharmaceutical companies, when you do development work of the kind the Institute did in the area of anticonvulsant drugs, for example?

How do you interact?

Dr. TOWER. This is done on a collaborative basis. These studies are done through contract. And in order to stimulate interest, we generally try to have a meeting with those pharmaceutical and academic people interested in developing new drugs and explain what we want, and then we put out the appropriate RFP's for screening of various types of compounds.

The program at the present time, I can't give you precisely the number of parties involved in the epilepsy drug screening program, but it is of the order of 130 at this point, most of them pharmaceutical concerns, but some of them academic departments of pharmaceutical chemistry and that sort of thing.

They are all funneled into a common contractor that we have at the University of Utah for screening by standard animal screening techniques for anticonvulsant drugs, and then out of that, we pull those that appear to be particularly promising on the basis of the animal studies, as well as the chemical structure. We are not interested in just more and different barbiturates, for example. We are looking for new compounds of novel structures that will give us a much more efficient and novel aproach to the epilepsy treatment problem.

It has been very successful. We have had a great many takers on this.

Of course, the key to it is that we are putting up most of the money.

QUESTIONS SUBMITTED FOR RESPONSES

Senator SCHWEIKER. I would like to submit for the record some questions from Senator Mathias to your Institute.

[The following questions were not asked at the hearing, but were submitted to the Department for response subsequent to the hearing:]

AUTISM

Question: Is there any new research on the horizon for autism?

Answer: Future directions for research on early infantile autism should focus on epidemiological studies to accurately determine the incidence, prevalence and risk factors associated with the disorder; particularly those factors in pregnancy, birth and the neonatal period. Children with infantile autism should be studied in conjunction with children with other neurological disorders showing autistic behavior in an attempt to identify clues to the basic neurodysfunction in infantile autism. Multidisciplinary studies in neurophysiology, neuropsychology, biochemistry, neuropathology and genetics should be pursued. The reasons for slow language development, or the lack thereof, need further study. Specific studies should focus on groups of autistic children who display special talent in music or other areas not in keeping with their overall development. Research is needed to develop successful treatments to improve the life quality of the autistic child and adult and their families. The most promising areas to be investigated are behavior modification, alternatives to verbal language, and neuropharmacology. The NINCDS is encouraging investigators to submit scientifically meritorious research grant proposals addressed to any of these aspects of the problem.

EPILEPSY

Question: Will the FY 1980 budget allow NINCDS to implement more of the recommendations of the Epilepsy Commission than the FY 1979 budget?

Answer: No. The FY 1980 budget will allow us only to maintain the few recommendations implemented in FY 1979.

HUNTINGTON'S DISEASE COMMISSION RECOMMENDATIONS

Question: What recommendations has NINCDS implemented to date of the recommendations of the Huntington's Commission?

Answer: The NINCDS has implemented the National Tissue Bank program in cooperation with two Huntington's Disease--HD--Health Voluntary Organizations, one in Boston, and the other in Los Angeles. The Second International Symposium on Huntington's Disease was held in November, 1978. Conference highlights will be published this spring. The collaborative Venezuela research project will begin in six months. Voluntary research patient rosters of HD patients and families are being established this fiscal year. Modest progress is being made in increasing the number of talented investigators working on HD. The NINCDS has added the former Executive Director of the Commission for the Control of Huntington's Disease and Its Consequences to the staff of the Neurological Disorders Program. She will develop program activities in HD, Parkinson's disease, Alzheimer's disease and related neurological disorders of aging.

EPILEPSY

Question: In addition to the general inquires made by the Committee on the implementation of the Epilepsy Commission report, I would like to direct some specific questions regarding epilepsy.

What is the Institute currently doing in the area of anti-convulsive drug treatment? Are there any plans to expand the program?

Answer: The Institute has an active drug development program. A screening program is operated to evaluate new chemicals in mice for their ability to prevent seizures. More than 2,600 compounds, sent by medicinal chemists in academics or in the pharmaceutical industry, have been studied. A primate model of epilepsy is used to study the metabolism of new anticonvulsant drugs and to evaluate their efficacy. Also, other studies evaluate investigational antiepileptic drugs in the treatment of human seizures such as absence--petit mal, complex partial seizures--psychomotor seizures, and generalized tonic-clonic seizures--grand mal. There are plans to expand the program through such activities as (1) support of new centers for improved intensive treatment; (2) by developing new technologies for the measurement and effective treatment of infantile spasms; (3) by improved screening techniques employing other animal and chemical tests to learn more about the mechanisms of action of anticonvulsant drugs; and (4) by stimulating synthesis of new chemicals by support of grants. In addition, a contract is planned to study the toxicology of promising compounds found in the screening process and encourage their further development.

Question: Have there been any advancements in science technology which improve the physician's ability to treat patients with seizures?

Answer: Great strides have been made to aid the physician treating the patients with seizures. In many locations throughout the country, and in the NIH Clinical Center, seizures are recorded with closed circuit video recordings, and simultaneous electroencepthalograms--brain waves--to determine the exact type of seizure, or seizures, a patient has. When a precise diagnosis is made by evaluating the seizures recorded on videotape and the electric manifestations of the EEG, the appropriate drug to the seizure type may be prescribed. Also, antiepileptic drugs and their metabolites are studied in patients so that effective treatments may be tailored to the patient. More than 50% of patients so studied have been improved from their previous condition; prior to admission they were considered virtually hopeless.

REYE'S SYNDROME

Question: I would be interested in having information for the record regarding any new research and/or progress in the areas of Reye's Syndrome and autism.

Answer: In June 1978,--with partial support from NINCDS and funding from several Canadian government agencies and two of the Reye's Syndrome voluntaries in the United States--a conference on Reye's Syndrome was held in Halifax, Nova Scotia. More than 150 participants representing virtually all the centers or groups concerned with Reye's Syndrome attended. With early optimal management of patients with Reye's, survival rates now run over 80% as compared to 50% several years ago. Neurological sequelae appear in 10% or less of survivors except for infants under one year of age. Reye's Syndrome is a complex disorder which appears to be multi-factorial in nature and multi-system in involvement. The question asked by several groups is the role of viral infections in the etiology of Reye's Syndrome. Exposure to an acute viral infection in and of itself does not necessarily produce the disease. Genetic susceptibility and perhaps also exposure to some environmental toxin are also implicated. The study of the pathological changes in the liver and brain is of great interest and likely to be of considerable importance for our understanding of the disease. Recent data from the Center for Disease Control associate Influenza A--the Russian Flu strain--with an increase in cases in early 1979. We are working with a group in Michigan to develop a clinical program project on Reye's Syndrome. This year we have initiated support of a study on a factor found in serum of Reye's patients which impairs function of isolated rat liver mitochrondria and provokes structural alterations reminiscent of those in the human disease. Another recent award to Albany Medical College in New York will support exploration of an animal model to evaluate the metabolic abnormalities seen in Reye's Syndrome. This has great potential for testing therapeutic manipulations. An investigator in Cincinnati will assess neuropsychological function in children who recover from Reye's. This work will determine the relationship between the acute clinical disease and recovery of neuropsychological functions and identify appropriate rehabilitative strategies.

AUTISM

The Communicative Disorders Program has awarded a contract on the acquisition of language and communicative skills by speech and sign language in infantile autism. This project is an experimental study of the development of communicative skills by autistic children when language training involves only speech stimuli, only sign stimuli, speech and sign stimuli presented simultaneously, or speech and sign presented independently. The types of tasks most easily and most difficultly learned in each modality will be determined. Also, the study will examine whether there is transference of language learning between the auditory and finger spelling systems within the subjects at different points during treatment. Such research will indicate what the specific language learning difficulties of these children are and whether they are related to difficulties in speech perception.

Studies have continued in the Developmental Neurology Branch, Neurological Disorders Program, on the 14 autistic children identified in the NINCDS Collaborative Perinatal Project. Earlier published work reported increased maternal vaginal bleeding during the second trimester of pregnancy as a potential risk factor. Umbilical cord blood samples have been examined for presence of certain antiviral antibodies but no significant results were found. Analysis of the placentas for abnormalities is underway. Tabulations have been prepared on the autistic children and controls for a series of findings from the 8-month developmental examination and the 1-year neurological examination in an attempt to identify predictive signs of autism.

HUNTINGTON'S DISEASE COMMISSION RECOMMENDATIONS

Question: The Committee has requested information regarding implementation of the recommendations contained in the Huntington's Disease Commission report. Among the recommendations made by the Huntington's Disease Commission were the development of a small grant program for research in the neurosciences and pilot programs for health care delivery. Does the Institute have any plans for implementation of either of these recommendations?

Answer: The NINCDS has instituted preliminary informal consultations with the NIH Division of Research Grants to determine the feasibility of a small grant program. In the meantime, investigators have been encouraged and are submitting an increased number of grant proposals in the areas of Huntington's disease and related neurological disorders.

The request for research grant applications for the Centers Without Walls indicates that these centers should be concerned with pilot programs for health care delivery. These programs would be coordinated with community health services to provide improved access to existing services.

Question: Has there been any action on the Huntington's Disease Commission's recommendation for a small grant program for research and neurosciences, in general?

Answer: Preliminary informal consultations are being held with the NIH Division of Research Grants to determine the feasibility of setting up such a program. Meanwhile, investigators are encouraged to consider the problems posed by Huntington's disease and related neurological disorders and to submit research grant proposals in these areas.

HIGH PRIORITY AREAS

Question: For all of your research programs funded by the NINCDS, Dr. Tower, what do you feel given tight budget constraints would be your highest priority areas, and what would the cost of these be?

Answer: The highest NINCDS priorities need to be assigned to:

a. Maintaining the 1980 high priority extramural research grant and contract activities at the levels previously committed for FY 1980. The amount required is $126,692,000.

b. Proving adequate funding for investigator-initiated new and renewal research grant projects competing for support in FY 1980. The 1980 President's Budget provides $23.3 million; the program need requirement is $60.3 million.

c. Maintaining the present level of scientific activity of the NINCDS intramural program. The minimum required is $32,964,000; the program need requirement is $35,434,000.

d. Maintaining the NINCDS research manpower development programs at the increased stipend level. The minimum required is $8,822,000, an increase of $1,500,000 for stipend increase; the program need requirement is $10,000,000.

e. Launching additional special initiatives in the areas of:

1. Positron Emission Transverse Tomography (PETT)	$4,250,000
2. Head and Spinal Cord Injury and Regeneration Research	2,200,000
3. Deafness Research and speech clinical research	3,500,000
4. Epilepsy Research	2,030,000
5. Research on Huntington's Disease and Related Genetic Neurological Disorders	2,200,000

HUNTINGTON'S DISEASE

Question: In your mind, what are the most important things that we should be doing now in the area of Huntington's Disease and Epilepsy?

Answer: The most crucial need in the area of Huntington's disease is to increase the amount of high quality research and recruit more talented and creative scientists into the study of Huntington's disease and related disorders. The research endeavor is relatively recent in Huntington's disease, given new impetus by the development of technologies which make it more amenable to study. In comparatively "underdeveloped" areas such as Huntington's disease research, the Institute can serve an important role in nurturing high quality research. The Centers Without Walls, recommended by the Huntington's Disease Commission, is a particularly valuable way of fostering interdisciplinary basic and clinical research on well-evaluated patients. The Institute is currently developing a Request for Applications--RFA--for one or two Centers. A Patient Roster, for which an Institute-sponsored Request for Proposals--RFP--will be issued shortly, will ensure that investigators have access to sufficient patient research volunteers, and the National Tissue Bank which the Institute currently supports, will provide investigators with needed tissues. The Venezuela Project, proposed by the Commission to study a unique population of Huntington's disease patients living in Maracaibo, Venezuela, is imperative to pursue because this genetic

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isolate is in the process of dispersing. Several investigators from NINCDS will be traveling to Venezuela in early April 1979 to determine the best methods of proceeding. Methods of stimulating new research hypotheses and recruiting scientists, such as interdisciplinary workshops, should be supported, and the training of basic and clinical investigators interested in neurogenetic and neurodegenerative disorders increased. A particularly pressing need is for the development of new drugs which may be used in treating Huntington's disease. The NINCDS has provided the nucleus of a focal point for these program developments by assigning an experienced staff scientist the responsibility for Huntington's disease and related research programs.

EPILEPSY

First, we should continue the preclinical (animal) and clinical development of new drugs for the treatment of seizures. Although a number of effective drugs are available, many patients are still poorly controlled and many suffer side effects from their medication. New drugs are needed since, according to the Commission for the Control of Epilepsy and Its Consequences, at least 200,000 Americans have seizures more than once a month; these patients need new more effective medications.

Second, we should continue research on the means of treating patients with intractable or uncontrolled seizures. This involves the precise diagnosis of seizure type so that the appropriate drug may be chosen and administered in a precise manner and in the correct amount.

Third, research support should continue on the basic mechanisms of epilepsy in the brain. Emphasis should be placed also on determining the mechanisms of action of presently available antiepileptic drugs.

Fourth, we should continue to study infantile spasms and other seizures of early childhood. Through this research, it should be possible to develop new, improved methods of treating patients with seizures. As more is learned about the various seizure disorders, our knowledge may be coordinated with our drug development program so that these new means of treatment may be applied.

Lastly, we should support the dissemination of scientific epilepsy literature. The support and exchange of scientific information on epilepsy throughout the world will further the understanding of epilepsy and its treatment. We should also support other organizations which obtain and distribute scientific information about epilepsy in furtherance of the common goal.

HUNTINGTON'S DISEASE

Question: Dr. Tower, please supply for the record what your funding plans for Huntington's disease are and how they relate to each of the Huntington's disease recommendations.

Answer: The following recommendations of the Huntington's Disease Commission have been implemented to date:

1. National Tissue Bank
   A contract has been awarded jointly from NINCDS and the National Institute of Mental Health in cooperation with two Huntington's Disease Health Voluntary Organizations to fund a Tissue Bank at Harvard University. This bank will provide for careful collection, storage, and documentation of tissues and biological fluids from patients with Huntington's Disease and other neurological and psychiatric disorders.

2. Second International Symposium on Huntington's Disease
   This symposium was held November 16-18, 1978, and drew an interdisciplinary group of several hundred investigators from over a dozen countries. A book of research highlights from this meeting will be published within the next several months.

Planning for implementing the following recommendations is in progress:

1. Two Centers Without Walls
   A Request for Applications--RFA--has been developed and is proceeding through the necessary clearances to solicit grant applications for the establishment of one or perhaps two Centers Without Walls for Huntington's disease. The Institute expects to be able to make one award in FY 1980.

2. Venezuela Project
   A collaborative research project with the Venezuelans is anticipated to begin within the next six months. Investigators from NINCDS will visit the proposed research site in Venezuela in early April to assess specific research needs and resources. These investigators and their Venezuelan counterparts will determine from this visit the best method of proceeding further in developing the research project.

3. Patient Rosters
   A Request for Proposals--RFP--has been developed and will shortly be released to solicit for the establishment of voluntary research rosters of Huntington's disease patients and families. Care has been taken to protect the privacy and confidentiality of those listed. The Institute plans to make an award in FY 1979.

4. Interdisciplinary Workshop Program and Neurogenetic Newsletter
   The Institute determined that this recommendation could best be implemented by a nongovernmental organization. Accordingly, grant applications in these areas will be sought.

5. Small Grants Program
   Preliminary information consultations are being instituted with the NIH Division of Research Grants to determine the feasibility of setting up such a program. In the meantime, considerable effort has been expended to reach both young and established investigators and to encourage them to consider the problems posed by Huntington's disease and related neurological disorders. As a consequence, we have seen a significant increase in the number of proposals of good scientific merit which have come to the Institute.

6. Pilot Programs in Research on Health Care for the Chronically Neurologically Impaired

The text of the Request for Applications for the Center Without Walls indicates that these Centers should be concerned with pilot programs and feasibility studies which would lead to the development of specific programs of health care delivery. These programs would be coordinated with community health services to provide for integration and improved access to existing services. In addition the NINCDS has submitted and has had accepted a proposal to implement the relevant recommendations of the HD Commission as one of the projects in the DHEW Long-Term Care Demonstration and Evaluation Project. The NINCDS project is entitled: Continuum of Care for Huntington's Disease and related disorders--a prototype. A decision on implementation of the DHEW Project is awaited.

7. Coordination of Health Services--in collaboration with the Center for Disease Control

No specific plans for collaboration with the Center for Disease Control have been developed at this time. Programs developed in the Centers Without Walls, however, should seek to pilot test service coordination and delivery programs which may ultimately be transferred to the CDC under the aegis of their Chronic Diseases Program.

8. Increased basic and clinical research on Huntington's disease in particular and in the neurosciences and neurogenetics in general

Modest progress has been made in increasing the number of talented investigators working on Huntington's disease. In order to recruit more scientists into the study of the neurological disorders of aging, the Institute has co-sponsored with the National Institute on Aging and the National Institute of Mental Health, the Second Alzheimer's Disease Conference: Behavioral and Social Aspects. Informal collaboration and cooperation is good among these three Institutes. Particular attention has been paid to the support of training of clinical investigators interested in the degenerative neurological disorders.

9. A Branch of Huntington's Disease and Related Disorders

The Neurological Disorders Program has recently added to its staff the former Executive Director of the Commission for the Control of Huntington's Disease and Its Consequences. She will be working to develop program activities in Huntington's disease, Parkinson's disease, Alzheimer's disease and related neurological disorders of aging.

NEW GRANTS

Question: Because of these strong funding increases in fiscal year 1979 for Huntington's Disease and epilepsy programs, you were able to fund several new grants and contracts.

What will a level funding budget request do to new proposals and initiatives in this area in fiscal year 1980?

Answer: In fiscal year 1979, the number of new grant applications with a priority score better than 250 was greater than anticipated at the time of budget planning. Therefore, only a relatively few new grants relevant to Huntington's Disease or epilepsy will be awarded in FY 1979. These new grants awarded in 1979 will be maintained in FY 1980, and funding of at least one Huntington's Disease Center Without Walls grant is planned for FY 1980. It is anticipated that some research contracts will be concluded and phased out in FY 1980, thus allowing some funding of contracts for testing the toxicity of anticonvulsant drugs.

MULTIPLE SCLEROSIS

Question: Multiple Sclerosis, since the inception of its commission several years ago, has been an area which has received less and less attention in terms of the public's eye.

What are you doing in the area, Dr. Tower, and what plans to you have for the future, specifically, 1980?

Answer: The special report delivered to the Congress presented the budget obligations for activities related to Multiple Sclerosis as follows:

MULTIPLE SCLEROSIS

Obligations

1976	1977	1978	1979 Estimate	1980 Estimate
$9,590,000	11,095,000	11,776,000	12,750,000	12,750,000

These figures demonstrate that Multiple Sclerosis research has been and continues to be an important major area of concern for NINCDS. In addition to a significant intramural effort, we now support extramurally approximately ninety individual research projects and specialized clinical centers which conduct research in both fundamental and clinical areas relevant to Multiple Sclerosis and related demyelinating disorders. Last year we initiated a new clinical program project at the University of California at San Francisco dedicated to further testing of the hypothesis that viruses play an important etiologic role in Multiple Sclerosis. Although the cause of Multiple Sclerosis is unknown, ignorance of its etiology is not absolute and a large focus in the Multiple Sclerosis research program is devoted to etiology. Diagnosis of Multiple Sclerosis, particularly in the early stages of the disease, is notoriously difficult. Recently, work based on fundamental studies has led to the development of several new diagnostic tools for Multiple Sclerosis including, for example, measure of specific immunoglobulins in cerebrospinal fluid and a further refinement of assays to determine the immunological response of the patients to some specific antigens. In Multiple Sclerosis, characterized as it is by exacerbation and remissions, the search for factors which predispose to an exacerbation or which prolong remission is important. Work with patients at the MS Clinical Research Center in Los Angeles indicates that behavioral therapeutic modalities are useful in helping patients to cope with

the disease. Since there are no totally appropriate animal models, it is important to continue support for investigation of the disease in human beings. Studies of etiology, pathogenesis and possible treatments require carefully documented patients who can be followed longitudinally in a research setting. Our seven clinical program projects provide such an opportunity for the reasearchers associated with them. The Multiple Sclerosis Commission recommended that the Institute Director delegate to one member of his staff administrative responsibility for all research and development relevant to Multiple Sclerosis that is funded by NINCDS. The Neurological Disorders Program has conducted a search over the last several years to recruit such a person. I am happy to report that the search has been successful and that we hope to have him on board by May 1. We have been fortunate to recruit a dedicated neuropathologist/neurologist with an interest in Multiple Sclerosis who will act as the focus for the Institute's firm commitment to research in all aspects of Multiple Sclerosis. Despite any seeming lack of attention, Multiple Sclerosis is in fact receiving a great deal of research attention. It is a flourishing research area that has attracted many of our best neuroscientific minds. It is, however, an extraordinarily difficult research problem that constrains rapid progress.

AMYOTROPHIC LATERAL SCLEROSIS

Question: Between Fiscal 1976 and 1979, the NINCDS budget has increased nearly 42 percent. During the first three years of this period, the NINCDS supported ALS research at a level of $1.6 million to $1.7 million.

Why has support for ALS research failed to maintain the overall progress of the total NINCDS research program budget?

Answer: As background for this question, it is important to remember that for diseases like amyotrophic lateral sclerosis--ALS--whose cause, course, early diagnosis and treatment are still shrouded in obscurity, relevant research cannot be judged with great precision. What at one point in time might be considered basic research may turn out to be most relevant to ALS if it provides an answer or even a clue to the cause and possible treatment of the condition. Research in basic neuroscience may become highly relevant to ALS if it provides an answer or even a clue to the cause and possible treatment of the condition. Research in basic neuroscience may become highly relevant to more than one disease entity including ALS, and research pursued for the purpose of helping to understand seemingly unrelated disorders or disease processes may contribute most tellingly to our understanding of ALS. The increases in the total NINCDS budget seen between 1976 and 1979 have, in the large part, been devoted to support of research in the basic neurobiological processes through which the central nervous system functions. This undergirding is essential not only for our understanding of the brain but also is crucial in providing scientific opportunity for leads for research in ALS.

It is vital to generate new research approaches and ideas in our attempts to understand ALS. In 1976 and 1977, the Institute received only three new applications in research directly relevant to

ALS. However, as a result of increased interest and opportunity in the scientific community, in 1978 and 1979 to date, the Institute has received six new approved applications of which three were funded. The unfunded applications all received priority scores poorer than 300 and thus were judged on the basis of scientific merit to be unlikely to provide significant new information. Thus, we have been able to increase support for fundamental research in areas relevant to our understanding of ALS, but we have not received enough applications of sufficiently good research quality specifically related to ALS. We have been working over the last several years with the relevant health voluntary agencies to increase the pool of researchers knowledgeable of and concerned with the problems posed by ALS. Scientific opportunity must be demonstrated before researchers are attracted to a new area of research. I am confident that our increased support of fundamental research related to the nervous system will pay off both in terms of our understanding of ALS and in terms of allowing our investigators to ask questions more specifically related to the disorder.

ADVISORY COMMISSIONS

Question: The Congress has authorized and you have conducted several advisory commissions to counsel you on several areas including epilepsy, multiple sclerosis, and Huntington's Disease. The same comment can be made for several other Institutes as well.

In your opinion, are these commissions the best way to get at specific problems, or do they cause an over-emphasis, and possibly weaken the effective use of research funds by forcing funding into a particular direction when more productive research could be done in other areas?

Answer: The Advisory Commissions have made important contributions to the documentation of health care needs and approaches to the meeting of those needs. These areas are not among the primary responsibilities of the NIH and Commision recommendations on them usually have been directed at other agencies and departments.

For example, the NINCDS utilizes regular inputs from its scientific program advisory committees, its National Advisory Council and ad hoc task forces for reviewing public needs, the scientific status and scientific opportunities in the several research areas of NINCDS responsibility. The reports of these advisory groups supplemented by information for scientific workshops and public forums with voluntary health agencies, have proven to be as effective for research program planning as have been the reports of Advisory Commissions. Any additional information derived from Advisory Commission reports has been of relatively lesser consequence and usually at great expense.

National Institute of Allergy and Infectious Diseases

STATEMENT OF RICHARD M. KRAUSE, DIRECTOR

BUDGET REQUEST AND PREPARED STATEMENT

Senator Schweiker. Now, we are ready for the National Institute of Allergy and Infectious Diseases.

This is Dr. Krause.

You are requesting $190,200,000 of that, and last year you received 191. We are glad to have a summary of your statement, Doctor. We will include your full statement in the record.

[The statement follows:]

STATEMENT OF RICHARD M. KRAUSE

Mr. Chairman and Members of the Committee:

As the 70's come to a close and we move into the 1980's, this is an appropriate time to review the progress reported in our Opening Statements of the past decade. And I have found in those statements a number of accomplishments:

*proof that rubella vaccine is effective in the prevention of birth defects;

*identification of the viruses causing hepatitis A and B and discovery of yet another type known only as nonA-nonB hepatitis;

*discovery of the chemical processes in the body that cause allergies;

*discovery that allergy "shots" block the effects of harmful antibodies in allergic patients;

*prevention of severe meningitis in the very young and pneumonia in the elderly through development of new polysaccharide vaccines;

*harnessing the power of molecular biology for human benefit through recombinant DNA technology;

*cultivation of the malaria parasite in the laboratory--a vital first step in developing new strategies for diagnosis and prevention.

And yet despite these achievements, many of the problems which we faced in 1969 are still with us. But there are reasons for optimism. Medical research does deliver new and unanticipated opportunities for the benefit of human health. In fact, the unpredictability of discovery is at the very heart of the scientific enterprise. For example, in the late '60's and early '70's, an NIAID grantee, Dr. Hamilton O. Smith, was working on bacteriophages--viruses that attack common bacteria. What an impractical matter that seemed to be! Why would anyone work on the viruses of bacteria when viruses attacking humans had yet to be conquered? But Dr. Smith's studies led to his discovery of the first of the "restriction enzymes", now hailed as essential tools in recombinant DNA research; and in 1978 he shared the Nobel Prize in Medicine for his discovery.

Despite the frequently held view to the contrary, we have yet to conquer most of the common infectious diseases. And as for immunologic and allergic diseases, we are only just beginning to apply to them the benefits of scientific research.

In this country, almost one-third of all patient visits to physicians are made for the treatment of infections and allergies. These may be as well-recognized as gonorrhea and as poorly defined as Legionnaires' Disease; as common as hay fever and as debilitating as persistent asthma. Furthermore, a complex interplay between infection and immunity may be a factor in the cause of many chronic diseases, such as rheumatoid arthritis, glomerulonephritis, and diabetes.

Future contributions will depend in large measure on the disciplines of immunology and microbiology, including virology. These disciplines, exploding with innovative ideas during the 1970's, have been the wellspring for new techniques being used today by scientists in many different specialized areas of medicine. Looking ahead to the 1980's, I believe we will see a decade during which the traditional approaches to infection and immunity will be revolutionized. This revolution will come through a chemical explanation of disease processes--and such knowledge must precede innovative approaches to new drugs and vaccines.

Infectious Diseases--In preparation for this revolution, I established a Virology Task Force to assist us in developing a strategy for improving the diagnosis, treatment and prevention of viral infections--the single most frequent cause of infectious diseases and indeed of all diseases in the Nation. Our National Advisory Council has examined the Task Force report and selected eleven

areas that should receive priority by NIAID. Embodied in this report are two very practical elements: a plan to develop drugs, and a call for new vaccines.

Few antiviral drugs have so far passed clinical trial. The drug "ara-A" has been successfully used to treat patients with herpes encephalitis, a highly lethal viral infection of the brain. Investigators are now trying combinations of ara-A and interferon, a natural antiviral agent, to treat other viral diseases. Although expensive and difficult to produce, interferon has shown promise. Further research is needed to determine its effectiveness.

As antiviral research goes forward, the Task Force recommends that we continue our efforts to develop vaccines for other serious viral illnesses, including hepatitis B. The status of other experimental viral vaccines, including new vaccines against influenza, are covered in a report on "Acute Respiratory Diseases" which is available to the Committee.

Despite my emphasis thus far on viruses, I assure you we are not oblivious to the importance of bacteria as a cause of many diseases yet to be controlled -- gonorrhea, hospital-acquired infections, pseudomonas infections in cystic fibrosis patients, and the already-mentioned Legionnaires' Disease, to name a few. The success of our bacterial vaccine program received national attention when three scientists closely associated with NIAID were presented the 1978 Albert Lasker Clinical Research Award. This award was given for development of vaccines, now licensed, against pneumococcal pneumonia and meningococcal meningitis. The pneumonia vaccine is now being tested for its ability to prevent middle ear infections that frequently lead to deafness.

The Immune System and Its Diseases--During the past decade, we have recognized the importance of the immune system as the guardian that protects the body from infectious agents, allergic substances, and possibly even tumors. One of the strangest and most unanticipated discoveries of recent years has been the recognition that the immune defenses that are marshalled against invaders can sometimes, for reasons still largely obscure, turn against the body itself. The immune system then produces antibodies and killer cells that attack and lead to injury and destruction of body tissues and organs. This pathological process is called autoimmunity, but I have referred to it as "the revolt from within". There are many autoimmune diseases including lupus erythematosus and myasthenia gravis.

Asthma, hay fever and other allergies, including those of the skin, differ from autoimmunity in that external substances, such as ragweed pollen, trigger the production of special antibodies that impart injurious effects. One area of allergy research that has attracted the attention of both the medical profession and the press this year has been the use of pure venoms in desensitization "shots" to prevent insect sting allergy.

Why do these diseases of the immune system occur? The answer to this puzzle may lie in entirely unanticipated dividends that have emerged from basic research on organ transplantation carried out in animals and man. This research has opened up the new field of immunogenetics--the science concerned with the genetic influences on immunity to bacteria and viruses, and the rejection of foreign substances, such as organ transplants. Indeed the direction of research on such diseases as arthritis, juvenile-onset diabetes, and even rheumatic heart disease is now focusing on the genetic control of immunologic processes and microbial infections. This increasing effort has led to an overwhelming demand for tissue typing sera from our Institute's Serum Bank, the world's major source of precious research material for these studies of the genetic control of susceptibility to disease.

In fulfilling its mandate from the Congress, NIAID last year established 4 centers for Interdisciplinary Research on Immunologic Diseases. An important objective of these centers is to accelerate the clinical application of new knowledge about the immune system and its disorders.

International Health--Beyond the shores of the United States, most particularly in developing countries, the impact of infections takes on the gloom of Malthus. Infection, overpopulation, and malnutrition contribute massively to the tyranny of the world's poor. There can be no fulfillment of the "right to

health" without research on new methods for preventing and treating major infectious diseases in the developing countries.

NIAID has long been at the forefront of research on diseases most prevalent in the developing countries. New research projects will be more focused on the problems of tropical medicine. These efforts will forge new linkages of communication between U.S. and foreign investigators so they can mount a common attack on the major ills that plague mankind. These include the diseases targeted by the World Health Organization--such as malaria, schistosomiasis and leprosy. Other research on diarrhea will complement the Institute's efforts at three new enteric disease centers, our own intramural projects on infant diarrhea, and the cholera research study in Bangladesh.

Recombinant DNA Technology and Risk Assessment--Our Institute has been deeply committed for several years to the exciting area of basic research now called recombinant DNA technology. Using this technology--a product of free-ranging basic research--scientists have employed common bacteria to produce medically important substances such as insulin and growth hormone. In a sense, bacteria have now been programmed in a very special way by medical science to produce valuable and important products, just as microbes were harnessed long ago to produce bread and beer. Much of the earlier controversy relating to hypothetical risks of conducting recombinant DNA research has subsided; the NIH guidelines have been revised; and the initial risk-assessment studies, using the mouse polyoma virus, have been completed by two NIAID scientists. These investigators concluded that DNA from this animal tumor virus, contained in recombinant molecules, is between 10 million and one billion times less infectious than the original whole polyoma virus. These results suggest that infection caused by bacteria containing recombinant viral DNA is highly unlikely. Risk assessment is a complex area of research, progressing in increments and these experiments represent only one part of a larger program in which the NIAID will play a role. The National Biomedical Containment Laboratory in Frederick, Maryland--which will provide maximum containment for hazardous research including certain recombinant DNA and risk-assessment research--is scheduled to open in 1981.

In conclusion, Mr. Chairman, our goal is to improve the treatment and prevention of allergic and infectious diseases. The NIAID budget request for FY 1980 is $190,202,000.

BUDGET REQUEST

Dr. KRAUSE. Thank you, Senator. I have a few remarks to make. Your comments and questions to some of the other Directors leads me to change the order of the points I will make in my summary remarks because I think I can answer some of your questions about the way we make decisions concerning the allocation of resources within the Institute.

ACCOMPLISHMENTS

First, let me say that these are a series of accomplishments of which we are proud: We hope these have made a difference in the health of the country. I would select several to mention here such as the pneumococcal vaccine that was licensed this last year. This prevents pneumonia in the older age group and was a development in many ways of an investigator from Philadelphia. Over a 10-year period he pursued this work. For this he was given the Lasker Clincial Research Award this past November.

That is one achievement. The meningitis vaccine is another, and the rubella vaccine still another advance of the 1970's.

In addition, there are a series of opportunities for the future from the basic discoveries that we have made. These include the discovery out on the NIH campus of the viruses that cause infan-

tile diarrhea. This can be a serious problem not only in this country but in particular the developing countries of the world. There has been the growth in the test tube of the malaria parasite and many more advances. But what I want to speak to briefly, and which I had not intended to do, was your question on how we decide where there are opportunities for progress.

You will see on page 2 from our annual report of last year, "A Matter of Opportunity," a pie diagram depicting the number of patients that visit a doctor's office each year in the United States, and these are the Government's statistics. On the average, every American makes about four visits to a doctor's office each year, over 800 million patient visits to a doctor's office each year. Approximately one-third of these visits are for infections or for allergies. Now, that means we need to learn from the patients what is causing their problems in determining our priorities and what needs to be done.

VIRUSES

When we look at that population of patients, one thing that stands out as a large and major problem is the problem of virus infections.

It stands out because there are at least 100 viruses causing infections as mild as the common cold, and as serious as encephalitis.

Second, except for one or two exceptions, we have no successful antiviral drug as we have in penicillin for bacterial infections.

So, a multiplicity of viruses, and no widely successful antiviral drug, such as penicillin.

Faced with these obstacles, and realizing that this is where one of our major health problems was located, several years ago we organized a virology task force to develop for us a report on where the opportunities were for the solution to this big problem of virus infections. You asked for this report last year, we now have it, and it is available.

The task force has given us a brief summary of 25 recommendations, and I have the backup material which I will hand over to your staff.

I might say, incidentally, that this backup material in five volumes will probably—I am rather proud to say—may very well be read as much or more than the summary because, as it turns out, it is used in graduate schools and medical schools as textbook material.

The NIAID Advisory Council reviewed these 25 recommendations of the task force, and identified the areas which they feel are of major importance to us, and on which we should focus our particular attention. I would be glad to submit for the record what those 11 areas are.

Senator SCHWEIKER. On what page are those 11 summarized?

Dr. KRAUSE. Those are not in there. That is the task force report. The Council recommendations are summarized in the material I am handing you.

Senator SCHWEIKER. Are they listed in the order of importance or priority?

Dr. KRAUSE. These 11 out of the 25 were thought to be the most important for the NIAID not only related to treatment, but also to control through prevention with possible new vaccines.

TREATMENT FOR VIRUSES

Senator SCHWEIKER. On the one that is listed here first for viruses, do we have anything on the immediate horizon that looks promising in terms of a viral agent to combat viruses?

Dr. KRAUSE. Currently we have two compounds that are being used. One that is called adenosine arabinoside—Ara A—which can be used for treatment of a fatal form of virus encephalitis.

This is the first beginning of the possible biochemical approach to developing an antiviral drug, similar, if you will, to the very first chemical drug, such a sulfonamides, which were developed for the treatment of bacterial infections.

The second drug under consideration is interferon and is one to which we are paying a great deal of attention.

Senator SCHWEIKER. Are you doing this in conjunction with the Cancer Institute?

Dr. KRAUSE. We are doing it jointly, in the sense that we work very closely with each other. Their clinical trials are concerned with the treatment of patients with those tumors that might be susceptible to this drug, and our clinical trials are concerned with very severe viral infections, such as hepatitis, or herpes infections in patients that have underlying malignancy.

FLU IMMUNIZATION

Senator SCHWEIKER. Do you feel we've done enough research in the area of flu immunization in order to conduct nationwide immunization programs?

Dr. KRAUSE. I was going to get to flu.

Senator SCHWEIKER. This is one question I'm going to ask you. I'm going to put the rest in the record, because we have covered that.

Dr. KRAUSE. I think that your question has a certain ambiguity to it, because a national immunization program could mean several things. What I think you are referring to specifically is the program which the Secretary has recommended. Yes, I do think that we have enough information to suggest that a large group of people that haven't received vaccine would be benefited if they could receive it.

I've read your Washington Post editorial, and I have it here. I recognize the importance of some of the questions you have raised. One of the several issues that was raised, Senator, in your hearings, and in your editorial, concerns the target population. A second issue is how much disease is really being prevented in the target population.

Those are issues or matters of interpretation of the epidemiological and statistical data which the Center for Disease Control has prepared, and they are matters over which experts argue.

We are certainly concerned about that, and we have—in order to address this issue for ourselves—with us this year, as an NIH Fogarty Scholar, England's expert in immunization, Sir Charles

Stuart-Harris, who has been a member of their royal commissions on many immunization programs. He is conducting an independent look at this matter of risk in the elderly and of efficacy.

He, himself, I might say, is one who has been very balanced in his judgment on the efficacy of this vaccine.

Senator SCHWEIKER. What does that mean?

Dr. KRAUSE. I mean the recommendation in England does target in on the older and high-risk populations. They do not reach quite as wide a group as we do but, at the same time, they have had now, for a number of years, a recommendation that the people who are at risk should get the benefit of vaccine.

We recognize that the present inactivated virus vaccine has imperfections and that was the other point in your editorial. There is a need for more research, and we recognize that, and, in fact, that is highlighted well in the Virology Task Force Report. Furthermore, I might say, it is also highlighted in the caliber of the talent of the people who work on it. I suspect there is no other single virus that has as many members of the National Academy working on it as has the influenza virus.

Maybe that is the problem. But at least it gives you some gage of the degree of interest.

Senator SCHWEIKER. Let me say, Doctor, you responded to my ambiguous question very well. In like manner.

Dr. KRAUSE. It's the nature of the virus.

NEED FOR MORE FLU RESEARCH

Senator SCHWEIKER. That is why they've dubbed it the "slippery disease."

I guess my question really should have been, Do we need more research done in flu immunization programs, in terms of basic research?

Dr. KRAUSE. Yes, sir. I think we do, and we need to learn more about the high-risk populations and the protective effect in those populations. We need more epidemiological research.

We need research on the virus itself and why is it slippery? What are the mechanics of this slipperiness?

Senator SCHWEIKER. I told you at the hearing that I support your request for it in this area, and my question is, How much do we have programed, or are we going to be programing, for the 1980 fiscal year in terms of more research?

Dr. KRAUSE. In 1979, for influenza alone, we are spending about $7 million.

That will not change very much in 1980. It will be about the same as in 1979. In other words, that will be an area that is relatively protected.

Senator SCHWEIKER. And what will the focus be in 1980?

Dr. KRAUSE. The focus in 1980 will be to continue efforts to develop an attenuated vaccine rather than a killed vaccine because, as you heard from Dr. Sabin, he and many others feel that if an attenuated vaccine were available, we would get much better protection.

We will also conduct studies to determine efficacy in the older populations to obtain more substantiated information than we now

have. We will also continue to try to find out why this virus has this instability, or slipperiness, as it was called by our social scientist friends.

VENEREAL DISEASE RESEARCH

Senator SCHWEIKER. Doctor, we seem to have a difficult time in terms of moving into the area of venereal disease research.

What do we plan for 1980, and what is the focus in your Institute?

Dr. KRAUSE. The plans for 1980 will be about a $200,000 increase over this year.

We currently are budgeted at about $7.3 million, and this will go up to $7.45 million, which is a slight increase.

Senator SCHWEIKER. The two figures were 1979 versus 1980?

Dr. KRAUSE. That is right.

Senator SCHWEIKER. You are doubling it?

Dr. KRAUSE. No. We are increasing it by about $200,000.

Senator SCHWEIKER. In view of this, I wonder if there is any sense in asking you why aren't we doing more.

Dr. KRAUSE. We at least will try not to do less.

Senator SCHWEIKER. I recognize that is an accomplishment.

Dr. KRAUSE. What will we focus on? We will focus on several problems. One problem concerns antibiotic resistance, or penicillin resistance of gonococci. This is a very major problem, and it is one which we now find is an epidemic among many bacteria.

I will pass to you an electronmicrograph of the actual gene that is transferred from a gonococcus resistant to penicillin to a penicillin sensitive gonococcus. Rather symbolically, the gene that possesses the antibiotic resistance characteristic has the figure 8, so you are behind the eight ball once you have acquired it.

So, the gene shaped like a figure 8 is responsible for penicillin resistance.

Senator SCHWEIKER. What can we do about that, Doctor?

Dr. KRAUSE. I think that the immediate thing that can be done is to do clinical trials with new antibiotics to see if they are effective in the treatment. That is a short-term, or halfway technology, if you will, which is important.

The longer term research is to understand this genetic mechanism, this special genetic mechanism among bacteria, and that will be the opportunity of recombinant DNA technology. I suspect that will tell us how this comes about, and more important, why it comes about.

ANTIBIOTIC RESISTANCE

Senator SCHWEIKER. Are we doing anything at the NIAID in that respect?

Dr. KRAUSE. Yes.

Senator SCHWEIKER. On this specific problem?

Dr. KRAUSE. Yes, indeed. This is one of our major areas—understanding with the most modern techniques, including DNA technology, the problem of antibiotic resistance.

Senator SCHWEIKER. Do we have a project going on now?

Dr. KRAUSE. I am sorry the chairman isn't here, because this is going on in Seattle.

Senator SCHWEIKER. Everything is. They ought to put something in Pennsylvania once in a while.

Dr. KRAUSE. I did happen to give a lecture on diabetes in Philadelphia.

This antibiotic resistance among bacteria has many broad implications. For example, Dr. Falkow calls this molecular epidemiology, and one of the exciting things that he can do in regard to hospital-acquired infections, is to detect these special genes by chemical techniques. He uses the detection of these special genes to identify the bacteria in wound infections, in operating-room-acquired infections, and in nursery infections. In other words, to trace the source of the spread of infections in hospitals.

So laboratory detection of the antibiotic genes in bacteria can have a broad, practical application. There is an article on this in the January 1979 issue of Medical World News.

Senator SCHWEIKER. When was this project begun?

Dr. KRAUSE. This particular project began in about 1972. I have forgotten the exact date.

RECOMBINANT DNA

Senator SCHWEIKER. Did the recombinant DNA feature start that early, too?

Dr. KRAUSE. The recombinant DNA research by Dr. Smith, which was one of the beginning landmarks, started about 1969. But in fact, the first observations that led to a lot of the recombinant DNA work had to do with the research on antibiotic resistance.

Senator SCHWEIKER. All right. Go ahead. Where are we?

Dr. KRAUSE. We've finished with antibiotic resistance.

VENEREAL DISEASE

Senator SCHWEIKER. I have one other question on venereal disease.

There are some other Institutes that are in this area, too?

Dr. KRAUSE. Yes, to some extent. Because one of the big problems in venereal diseases is herpes infection. There are perhaps at least 10 million people with herpes infections. The Cancer Institute is involved in herpes virus research, as is the Arthritis Institute and the Dental Institute.

LEGIONNAIRE'S DISEASE

Now, if I might mention one point: I know you would want to bring this up. That is Legionnaire's disease—just to say that we have worked with the CDC on this, and I think closely. We had, I think, a successful conference last fall.

We have issued a request for applications detailing the kinds of research that we feel investigators ought to address on this really important problem.

Senator SCHWEIKER. I saw a chart from CDC the other day at the hearing we were at, where there were so many outbreaks, in so many States, and so many separate cases.

I just wonder how close we are to isolating the organisms. I know it's in air-conditioning, and so forth. But what are you folks doing in this regard?

I say organisms. The climate, I should say, and the agent.

Dr. KRAUSE. The agent, as I'm sure you have heard, appears to be widespread. Of the 500 or 600 cases that are known to occur each year—although there may be more that we do not know about—many are associated with small epidemics occurring in local areas, some of which are in hospitals.

The agent does appear to be widespread, and perhaps distributed not only in such things as water towers, air-conditioning units, but also in soil. It may very well be a natural soil organism.

Legionnaire's disease probably is representative of a group of diseases which, in the past, we have called atypical pneumonia. When in medicine we call anything atypical or primary, that means we don't know what we are talking about.

However, of this whole group of diseases, or pneumonias, for which we have not in the past isolated an agent, part of these now can be put under the umbrella of Legionnaire's disease, for which the agent has been isolated.

Much more needs to be done, though, on why certain groups of people appear to be more susceptible to this infection—older people, as well as people who have a reduced immunity for other reasons, because of underlying disease, or immune-suppressive drugs for other diseases, such as arthritis.

Senator SCHWEIKER. What do you have programed in terms of research for the 1980 budget?

Dr. KRAUSE. We currently do not have any money programed until we see the grants that have come in, which are now in-house and are being reviewed. We will determine the quality of these applications from the scientific community.

Senator SCHWEIKER. Are you talking about fiscal 1979 now, or 1980?

Dr. KRAUSE. 1979.

Senator SCHWEIKER. You haven't had any come in yet, in 1979?

Dr. KRAUSE. We are reviewing them now, yes; but we will not know their quality until they go to May council.

Senator SCHWEIKER. I hope we have a high priority if we can find some.

Dr. KRAUSE. The very top priority applications should certainly be funded, and I hope that some of these will concern Legionnaire's disease.

So, it will depend upon the review process. If they come out as high quality applications, we will be able to fund them this year.

QUESTIONS SUBMITTED FOR RESPONSES

[The following questions were not asked at the hearing, but were submitted to the department for response subsequent to the hearing:]

ASTHMA AND ALLERGIC DISEASES

Question: What kinds of studies are being done by the Asthma and Allergic Disease Centers around the country?

Answer: Among studies carried out by the Asthma and Allergic Disease Centers around the country are those focusing on the regulation of serum IgE synthesis. It has been shown in man that certain immune cells are deficient in allergic individuals. This knowledge should lead to the development of ways to correct this deficiency and possibly to treat allergic people in a uniform fashion, irrespective of the cause of their particular allergy. Furthermore, in some persons with angioedema or urticaria -- different forms of hives -- a specific, possibly correctable serum enzyme deficiency has been found.

Studies leading to improved diagnosis of allergic individuals include development of enzyme linked blood tests for immunoglobulin E (IgE) -- the hallmark antibody of allergy. These tests are expected to result in accurate and economical means of diagnosis, possibly eliminating the need for skin testing in many instances. Additionally, the use of broncho-provocation tests in the diagnosis of asthma has led to a more objective definition of abnormal pathogenic mechanisms occurring in an individual patient. Methods have been improved to detect persons who may be at risk of developing reactions to penicillin or to dyes with special medications used in certain X-ray studies. In some cases these individuals may be pretreated, thus preventing possible severe allergic reactions. Finally, studies have led to improved treatment for persons with a variety of allergic disorders. A specific form of hereditary angioedema (a potentially fatal disease due to swelling of vital organs) can be successfully treated with Danazol; however, the development of other agents are needed because of undesirable effects of this drug in women. There has been great improvement of materials for treating persons with serious, potentially fatal allergic reactions to insect stings. Finally, for allergic individuals who require allergy shots, better materials, revised treatment schedules, and use of alternative means of administration (oral, nasal) have made possible a reduction in the dose and frequency of administration.

Question: We understand that you had planned to make four more awards for this program in fiscal year 1980. Will you still be able to do it with your budget request?

Answer: The President's FY 1980 budget did not provide for any increase in the number of centers, but will permit us to maintain the same number we are supporting in FY 1979.

IMMUNE SYSTEM

Question: Last year you discussed with the Committee the importance of the immune system in our bodies and the role that it plays. What programs are you doing in fiscal year 1980 and what other areas of research in this high priority area would you like to be working on?

Answer: We are committed to continuing and exploiting promising

leads in the following rapidly moving and highly important defined areas of the immune system: structure, function and physiology of the multicomponent cellular elements and their products; and genetic mechanisms controlling recognition of foreign invaders as well as allergic substances.

The success of organ transplantation depends on a firm understanding of genetic individuality and its effects on the immune system's ability to recognize and discriminate the histocompatibility markers on organ donor and recipient tissues that determine acceptance or rejection of a graft. Therefore, basic research on immunogenetics and application of its findings to human transplantation will be maintained. Furthermore, transplantation research has provided important leads on the genetic control of the immune system, especially genetic factors influencing susceptibility to infectious, allergic and other immunologic diseases.

The lymphocyte is clearly one of the most important cells in the immune system. Therefore we will maintain our effort to define the role of this cell in the immune process.

Areas of research that we plan to pursue include the following: the naturally occurring products of the immune system involved in its self regulation must be isolated, chemically defined and functionally characterized, a full understanding and availablility of these immuno-regulatory substances is needed if we are to manipulate the immune system in ways that will prevent infectious, neoplastic, allergic and other autoimmune processes, improve surgical organ or bone morrow transplantation and correct immune deficiency disorders.

It has long been recognized that the effectiveness of vaccination and immunization procedures can be enhanced by incorporation of nonspecific accessory materials (adjuvants) into vaccines. New knowledge of the immune sytem and modern day chemistry could be utilized both to manufacture more effective adjuvants and to eliminate the risk of untoward side effects in vaccine recipients. We believe that efforts directed to understanding cellular and molecular events in adjuvant action are timely and justified.

There is evidence that virus invasion may have implications in the occurrence of disease states in addition to those directly due to infectious process. It is known that viral infections can temporarily diminish immune competence thus compromising the host's defenses against other challenges such as neoplasia and possible allergic sensitization. Virus infections of cells lead to the display of virus components on the cell surface. This inclusion of viral components in the cell membrane disturbs the host's immune recognition mechanism which, in turn, can lead to autoimmune disorders such as systemic lupus erythematosus, and other chronic diseases.

We have learned that parasitic infections -- important international health problems -- are complicated by an allergic process secondary to the presence of the parasite. To learn how this allergic reaction can intensify the tissue damage following

parasitic infection, we plan to study the role of the eosinophils and Immunoglobulin E antibodies in such diseases as schistosomiasis and filariasis, as well as hookworm and ascariasis which are endemic in certain sections of the United States. This work may explain why and how individuals can exhibit either immunity or allergy to the same parasitic organism.

We believe that our present activities are directed at the most important problems and provide the best opportunities. We are therefore more interested in assuring that these are adequately supported than in diffusing into still other areas.

RESULTS

Question: Has basic research on the immune system yielded anything in the past year?

Answer: Yes, and I would like to briefly describe a few important advances that show great potential for clinical application.

Research on experimental animals has demonstrated that there is an internal mechanism for self regulation of the immune system. This self regulation is due to different "sets" of lymphocytes which either enhance or suppress the immune response. It is now possible to separate these cells from each other and isolate them. In very early clinical application, the appropriate set of lymphocytes has been given to patients to correct their abnormal immune defect.

Studies on the maturation of lymphocytes has revealed several important stages in their development. Immune disease can result if this maturation is arrested prematurely. For example, a disease in which there is a lack of a certain type of antibodies (hereditary agammaglobulinemia) represents a failure of maturation from precusor bone morrow cells to mature lymphocytes. Correction of this defect may be at hand by extracting and recovering from the thymus gland a hormonelike substance called thymosin. Thymosin is currently a substance under intensive study because of its important role in stimulating the maturation of lymphocytes.

Great strides have been made in determining the chemical reactions in the body that cause the inflammation in asthma and allergic diseases. Allergic substances inhaled into the nose or the lungs, for example, are confronted by a special type of allergic antibody termed IgE. The reaction between these special antibodies and the allergic substance activates a special group of cells known as basophils. These cells release a series of well defined chemical substances that cause the symptoms of hay fever, asthma and hives. Understanding this chain of events and these precise chemical reactions provides new opportunities to design specific approaches to drug therapy.

Question: In your opinion, what are the most important advances made with funding from your Institute in the past few years?

Answer: In addition to the developments, that have clinical

application, which I have mentioned, the following advances have been of major importance to the science of immunology.

1. Determination of the chemical structure and function of antibody molecules and the genetic control of their production.

2. Development of hybrid lines of lymphocytes known as hybridomas. This innovative technology is being exploited to produce immunological substances for basic research and clinical medicine. For example, human tetanus antitoxin has already been produced by this technique.

3. Identification of the genetic mechanisms that control the recognition of foreign materials by lymphocytes and macrophages. This recognition is the vital first step in stimulating the immune response to invading bacteria and viruses, cancer cells, and allergic substances.

4. Transplantation research has revealed that occurrence of distinctive antigenic markers (histocompatibility antigens) on the surface of the body's cells is under genetic control. Blood tests to detect these markers are employed in organ transplantation to "match" as closely as possible these cell surface markers between the patient and the donor of an organ. A close match improves the survival of the transplanted organ. Transplantation research has opened up new avenues to investigate the cause of chronic diseases. For example, the transplantation blood tests are also employed to determine a predisposition to certain diseases such as ankylosing spondylitis, juvenile onset diabetes, and many others.

5. Identification, isolation, and characterization of serum factors, known collectively as complement, and chemical substances from platelets and from white and red blood cells. These substances and factors participate in an intricate series of chemical reactions that lead to bacterial killing, virus destruction and tumor cell death.

VIRAL DISEASES

Question: Could you summarize for us the recommendations of the Virology Task Force whose report was recently published?

Answer: The complete six-volume report of the Virology Task Force has been reviewed and endorsed by the Institute's Advisory Council. It is now being distributed. The Council, at its meeting in January, 1979, adopted the report of a subcommittee which had condensed the Task Force recommendations into 11 recommendations appropriate to the NIAID, and estimated the funding increase needed over the next 5 years to meet the Task Force recommendations. These funding level increases reflect priorities. There follows an abstract from the Council report:

Areas to be emphasized and expanded:

	Annual Investment* 1978	1983**
VIRAL INFECTIONS		
1. New techniques for detection, isolation and propagation	$1,700	$5,000
2. Epidemiological studies	3,900	9,000
3. Persistant virus infection and chronic disease	2,200	5,000
4. Mechanisms of injury	3,700	7,000
5. Live virus vaccines	1,600	5,000
6. Inactivated virus vaccines	1,800	4,000
7. Antiviral drugs	7,000	17,000
8. Environmental control of transmission	550	2,000
BASIC VIROLOGY		
9. Structure and multiplication	15,200	25,000
10. Viruses as reasearch models and tools	4,900	12,000
TRAINING		
11. Training of new Ph.D's and M.D.'s	1,200	4,000
TOTALS	$43,750	$95,000

* $ X 1,000
** in FY 1979 dollars

Question: What specific plans do you have for implementing these recommendations and how are they reflected in the fiscal year 1980 budget?

Answer: The FY 1980 budget does not reflect these recommendations which were not available until January, 1979. We do expect an increase for virology research in FY 1979 over the 1978 level due to the increased number of grants that will be paid and some increase in clinical studies on antiviral drugs. The FY 1980 budget will maintain the 1979 levels. The Institute expects to address these needs more fully in its FY 1981 submission. I should note that the Council in making its recommendation, was cognizant of the levels of support to virus research by other NIH Institutes, notably the NCI which has a larger overall investment than the recommended levels for NIAID. We were cautioned that if that level of support were decreased the NIAID might well have to seek to make up the deficits in its areas of mission responsibility.

INTERFERON

Question: I understand the subject of Interferon, a human-made drug, was discussed with the Cancer Institute earlier this morning. Could you please go over with us what you feel the potential for Interferon is and what you plan to do with it in fiscal year 1980?

Answer: Interferon is a substance produced by cells infected with virus or subjected to certain other stimulation. It has been studied intensively as a host defense mechanism against virus infection, since its discovery in 1957. It has no direct effect on viruses, but stimulates cells in such a way that they resist virus growth. The possible usefulness of interferon lies in the demonstration that it markedly enhances the resistance of human body cells to a large number of viruses that cause serious infection. Interferon is species specific. Supplies for studies in man must be obtained from stimulated human cells, usually white blood cells. The only supplier of human interferon from white blood cells in quantity is in Finland.

More than one type of interferon occurs. Interferon from malignant cells can be produced in laboratory cultures. This interferon can be used in cancer patients, but not in patients with virus infections. The antitumor effect is probably associated with other properties of interferon such as its toxic effects on cells and not its antiviral action.

The NIAID has conducted a number of clinical studies demonstating efficacy of interferon against certain virus infections. In the past several years there have been studies which have yielded promising results in the treatment of chronic hepatitis B infection and disseminating herpes zoster. We intend to continue these studies in 1980 searching for the minimal effective dosage and the value of combination of interferon with other antiviral drugs in treatment. The work is slow because of its costs and limitations on quantities of interferon. Treatment costs about $1,300 per day and may require 4 or more weeks in hepatitis patients.

We believe interferon as we now know it has limited potential for clinical usage until there is much more basic research on the mechanism of action and applied research on increasing production and purification. Great efforts are being made to synthesize it in the laboratory or to find nontoxic drugs which will stimulate its manufacture by the individual patient.

Question: Is it correct to assume that if Interferon is a natural therapeutic agent, could it also have an impact in allergy and infectious diseases as well?

Answer: I have previously outlined some of the activities of the NIAID on interferon. Essentially, we are providing vigorous support to basic research on the substance, its biochemical structure and mechanisms of action, its effects on cells and the whole animal, on methods for its purification and obtaining greater yields at lower costs, and a variety of other research objectives. If we can determine its biochemical structure we may be able to make it in the laboratory. Alternately, recombinant DNA technology may allow its volume production at low cost.

Question: Dr. Krause, who is the Director of the Allergy Institute-- what are you doing to test interferon and what are your plans in the future?

Answer: We are exploring various chemical compounds that stimulate interferon production by the whole body and are working closely with the NCI to evaluate one such compound developed by one of our intramural scientists. As previously noted, we are also pursuing exploratory studies on its value in the treatment of life threatening virus infections such as hepatitis B virus. The NIAID is the principal source of HEW support for research on all antiviral drugs.

TROPICAL DISEASES

Question: Last year, the Committee expressed strong support for a tropical disease research program within your Institute.

What have you done in fiscal '79 to implement this program and what are your plans for fiscal 1980?

Answer: In 1979 we expect to increase our support of research on tropical diseases by an estimated $3 million. We solicited applications for multidisciplinary grant and and other grant applications, receiving 15 multidisciplinary applications and 37 other grant applications. These are now undergoing scientific peer review and will be considered at the May, 1979 Advisory Council meeting. We also have announced an International Fellowship award and will soon solicit Young Investiagtor awards. Support to our intramural program has been increased, particularly in the dynamic malaria and infantile diarrhea programs. As Director of the Institute, I have participated in planning sessions for the World Health Organization (WHO) tropical diseases research program and we maintain close liaison with them.

Under the President's budget for FY 1980, we have planned a further $2 million increase as a result of the initiatives mentioned above and a further solicitaiton for grant applications recently issued. We hope to receive enough scientifically meritorious applications to allow this increase to take place in competition in the grants in other areas.

Overall, the NIAID expects to increase its total portfolio of research related to tropical diseases from $20 million in 1978 to $25 million in 1980. This is the major governmental program of research in tropical diseases.

Question: What areas do you think we should be working in and which hold the most promise in the area of tropical disease medicine?

Answer: We agree with the WHO selection of priorities, including diarrheal diseases. At the moment, progress in malaria and infantile diarrhea seems to hold the most promise. The knowledge base warrants efforts to develop vaccines against both, but success cannot be assured until much more exploration is completed.

NATIONAL LABORATORY

Question: Please bring us up-to-date on the development of the National Biological Containment Laboratory at Frederick, Maryland. What do you expect to do at this specific laboratory that cannot be done on the NIH campus?

Answer: The National Biomedical Containment Laboratory at Frederick, Maryland is proceeding on schedule. Architectural and engineering specifications for the renovation of existing buildings have been completed and a contract for the renovations should be completed soon. These activities are being carried out under contract by the NCI and are generally supervised by the Division of Engineering Services of the NIH.

When completed these laboratories will provide a full capability of working at any level of biohazard up to and including "P-4"

as defined in the NIH Guidelines, suitable for the most hazardous microbiological research. These laboratories will be available to any scientist who has a clearly demonstrated need for such containment and will be the only P-4 research laboratory available generally to the scientific community in the nation. While some facilities with lesser containment levels exist on the NIH campus and elsewhere, these are limited.

A very small amount of P-4 space has been developed on an interim basis at Frederick and has allowed NIH scientists to proceed with several important risk assessment experiments requiring this level of containment. When the national facility is completed, research should proceed at a faster rate because several groups of scientists will be able to work simultaneously.

Question: Does your budget and that of the Buildings and Facilities account reflect the proper amount of money necessary to have a safe working environment at this center?

Answer: The FY 1980 President's budget provides the funds needed for that year although some reprogramming authority may have to be requested by the NIH. We shall have to request additional funding and staffing for FY 1981 to support the beginning of operations and to carry out the broad research program on recombinant DNA risk assessment which is necessary for any future modifications to the guidelines to ensure safety of such research.

Question: When do you expect that it will be operational?

Answer: The national facility is expected to be occupied in 1981.

PROMISING RESULTS

Question: In which of your many areas of research do you feel that we have the most promise for results or breakthroughs in the near future, doctor?

Answer: In reply to other questions I have enumerated several breakthroughs related to the immune system, asthma, allergic and immunologic diseases. To recount briefly, these were the potential for manipulation of the immune system to minimize disease processes; the identification of the specific chemical processes in allergy and the development of special drugs to combat these processes; and the growing recognition that the genetic control of the immune response influences the occurrence of a number of chronic and degenerative diseases in which viruses trigger the immunopathological process (juvenile diabetes, spondylitis, Reiter's syndrome, certain leukemias).

The report of the Virology Task Force identifies possible breakthroughs in a number of areas that cannot be summarized here. To mention a few, the feasibility of a vaccine against hepatitis B virus infection; the development of specific antiviral drugs which will inhibit intracellular viruses without damage to the cell; and the identification of rotaviruses as a principal cause of infantile diarrhea throughout the world and the possibility of a vaccine.

Perhaps the major promise lies in exploitation of recombinant DNA technology which has already been used to produce human hormones in the laboratory. The potential benefits include low cost production of pure antigens for vaccines and antibodies for correction of genetic immune diseases. Examples include: hemagglutinins of influenza viruses or the immunizing antigen of pertussis, devoid of other components of the virus or bacteria that are responsible for toxic effects; and antibodies to pneumonia and meningitis to combat infection. Interferon would be produced if the genes responsible for cellular manufacture of this substance can be identified. Overall, the potential is so broad and the objectives so promising, I expect an avalanche of new, useful products from this technology during the next decade.

Although I cannot point to immediate breakthroughs for our most difficult health problems, I do want to say that we are increasing our knowledge of the viruses and bacterial responsible for many acute infections, especially those of the respiratory tract. The problems are so great in these commonest cases of human illness and the need so urgent, we feel that we must devote a considerable effort to maintain progress. The sexually transmitted diseases represent another group of viral and bacterial infections responsible for much human illness. The feasibility of a vaccine against gonorrhea is now being tested as are antiviral drugs to alleviate the problems of herpes genitalis. The role of chlaymidiae in nongonococcal urethritis and vaginitis is established and opens the pathways to specific treatment and prevention.

Finally, I should mention tropical diseases or more specifically the parasitic diseases. A new science of immunoparasitology has emerged. This science is concerned with the special ways the body develops immunity and it is on this that much of the World Health Organization's programs to tropical diseases such as malaria, schistosomiasis, leishmaniasis, filariasis and onchocercosis depends. Such growth of research in conjunction with the successful growth of human malaria parasites in the laboratory raises the possibility of vaccines for these diseases. Immune reactions appear to play an important role also in the destructive processes in vital organs in parasitic diseases. Parasites are providing novel model systems for research on immune phenomena, particularly the role of the eosinophil and antiglobulin E (IgE) in allergic reactions. NIAID intramural scientists have identified a new group of viruses (rotaviruses) that commonly causes diarrhea in infants and is often fatal in malnourished infants in tropical countries who do not have access to proper treatment. These viruses may cause more than half of infantile diarrhea in the U.S.; this discovery may lead to a preventive vaccine that would be the single most important development to prevent infant mortality in the developing countries.

Question: Is your budget allocated so that those are the areas receiving funding necessary?

Answer: We try to allocate our resources to capitalize on opportunities that promise benefits for prevention or health care while not suppressing the individual investigator-initiated research, which will provide us with the knowledge we need to

tackle the many still unsolved problems. Since about 80% of our extramural research funds are devoted to the support of such investigator-initiated research, we can devote only relatively small amounts to the more applied and developmental work. In the 1980's we can foresee that basic research will lead to new opportunities for developmental research beyond our current resources.

PRIORITIES

Question: Dr. Krause, in your opinion, what are the most important priorities of your Institute given the "state-of-the-art" right now?

Answer: I would list our highest priority research as being:

- Immunology including (1) structure and function of the immune system; (2) immune diseases such as asthma, allergies, and autoimmune disorders; (3) genetic control of the immune reaction including improved acceptance of organ and bone morrow transplants.

- Microbiology (viruses, bacteria, parasites, fungi) with special attention to (1) microbial biochemistry, antigenic structure and genetics; (2) virus diseases including influenza, other respiratory diseases, and hepatitis; (3) antiviral drugs; (4) bacterial diseases including sexually transmitted diseases, pneumonia, and meningitis; (5) tropical medicine including parasitic diseases, leprosy and diarrheal diseases; and (6) exploration of recombinant DNA technology including risk assessment of the technology and its products.

Our policy is to maintain momentum on this broad front of problem areas by giving maximum support to the best individual, investigator-initiated projects including the most productive of scientists in the intramural programs. The Institute will also maintain some degree of momentum in the transfer of knowledge from the bench to bedside through its centers, and work to develop vaccines and antiviral drugs in its contract programs.

CDC COORDINATION

Question: You have two specific programs that should be specifically coordinated with the Center for Disease Control--the first is venereal disease and sexually transmitted disease programs and the second is tropical diseases. Please tell us what and how you coordinate these programs; what you are doing with CDC, and what other programs you are involved with?

Answer: We have a very close liaison with the CDC in many areas of common interest including the sexually transmitted diseases, tropical diseases, influenza, hepatitis, and other virus diseases, legionnaire's disease, hospital acquired infections, epidemiology, and the impact of allergy and infectious diseases on society. These efforts are coordinated through frequent exchanges between Dr. Foege and me, by inclusion of appropriate staff from both

agencies on planning and review committees, by collaboration in research activities, and by other staff interactions. For instance, we jointly sponsored the Conference on Legionnaire's Disease in 1978, jointly prepared and sent to the Congress an annual special report on Sexually Transmitted Diseases, and with the Bureau of Biologics jointly supported the Conference on Pertussis (whooping cough) in 1978. NIAID is part of the interagency Planning Group on Pandemic Influenza, and we have collaborated closely in the clinical trials of influenza vaccines in 1976 and 1978.

In general these collaborative efforts recognize the strengths of the CDC in epidemiology, certain types of laboratory studies and field work and the strengths of the NIAID in laboratory and clinical research. The Bureau of Biologics of the Food and Drug Administration is involved in many of these joint activities.

INSTITUTE INTERACTION

Question: Dr. Whedon and Dr. Krause, who is the Director of the Allergy Institute, we are told that possibly infections and other environmental factors may play a large role in arthritis. Would you comment on this for us, please, and tell us what you doing in terms of inter-institute cooperation in this area?

Answer: Several of the connective tissue diseases and arthritic disorders with which NIAMDD is concerned are associated with hypersensitivity reactions and inflammation. These indicators of an immunologic process may well be triggered by infectious agents. Rheumatoid arthritis, systemic lupus erythematosus and Reiter's Syndrome can be cited as some examples of conditions in which immunologic mechanisms are being shown to play important roles in development of disease.

Because of NIAID's involvement in research on immunologic and infectious processes and their genetic basis, it is important to join forces with NIAMDD in attempting to assure that the most promising investigative approaches to the immunologic basis of the arthritis syndromes go forward. Accordingly, through dual assignment of research proposals we seek to share responsibility for grant awards: NIAMDD where the focus is on the affected target tissue ; NIAID where the thrust is directed toward immune-related mechanisms or relevant infectious agents. As an illustration, NIAID has given unqualified support to several basic science, clinical immunology and immunopathology investigators working in areas that contribute to the endeavors of NIAMDD Arthritis Centers.

We seek to extend these cooperative approaches through active liaison between NIAID and NIAMDD, and through the Trans-Agency Arthritis Committee that is responsible for the coordination of all federally supported research in arthritis and connective tissue diseases.

Senator SCHWEIKER. Now, Mr. Leon Schwartz, the Executive Officer of the National Institutes of Health, will testify on the buildings and facilities accounts for NIH.

Mr. Schwartz, you are requesting $3,250,000 for fiscal year 1980. For fiscal year 1979, you have requested $30,950,000, excluding the $37 million for the new child health facility.

I understand that you have asked for a rescission of this amount, and I just wonder if you have any comments about this rescission.

Otherwise, we have a few questions for the record.

Mr. SCHWARTZ. Yes, sir. In last year's President's budget, we had $27.7 million for the last installment of the modernization of the clinical center, the so-called ambulatory care research facility. So that is what represents the reduction from fiscal year 1979 to fiscal year 1980.

You are quite correct that there was an appropriation for the child health facility, and the administration has proposed a rescission for this building.

The chairman this morning did mention the fact, and there was a dialog between Dr. Fredrickson and the chairman. If you like, I could repeat some of the comments that we made at that time.

Dr. FREDRICKSON. Would you like us to repeat those, Mr. Chairman?

Senator SCHWEIKER. You made them here this morning?

Dr. FREDRICKSON. Yes, sir.

QUESTIONS SUBMITTED FOR RESPONSES

Senator SCHWEIKER. I just wanted to make sure they were in the record. I just wanted to renew our requests to have all questions for the record and transcripts back to the committee, please, in 7 days, so we can go to press.

[The following questions were not asked at the hearing, but were submitted to the department for response subsequent to the hearing:]

CHILD HEALTH RESEARCH FACILITY

Question: What was the initial estimated cost for construction of the National Institute of Child Health and Human Development?

Answer: The preliminary construction estimate of $10 million which included on-grade parking for 260 cars was made in 1965 prior to initiation of design. The design was essentially completed in 1971; at that time the projected construction cost including a 650-car multilevel parking structure was estimated to be $21 million.

Question: What is the current estimate?

Answer: The current estimate is $37.0 million. (FY 1979)

Question: What is the estimate if funds were to be provided in FY 1981?

Answer: The estimate for funds in FY 1981 would be $44.0 million.

COST OF FACILITIES, GENERAL ACCOUNTING OFFICE REPORT

Question: January 11, 1979 General Accounting Office Report of the financial status of major Federal acquisitions appears to show that for your Clinical Center Facility, the original estimate was $63.2 million. GAO now says that the current estimate is for $105 million. Also the Lister Hill Center which was $15 million is now $26 million and the Environmental Health Sciences Center which was $51 million is now $71 million. This is a rather confusing report and I am wondering if you could explain these figures to us in terms of if more funds will be needed?

Answer: The difference between the preliminary estimates and the current estimates are due to the escalation of construction costs by inflation over the five-or six-year span between original project concept and the year that the construction funds are appropriated. There have been no increases in cost since the projects were appropriated.

For example, the Engineering News-Record Building Construction Cost Index for September 1978 is 2.12 times greater than the cost index for April 1970. At this time we do not anticipate any need for additional funds to complete these projects.

NIH MODERNIZATION AND RENOVATION PLAN

Question: Last year, the Committee expressed its concern over the renovation and modernization of the existing facilities on the National Institutes of Health campus. It is our understanding that many of these facilities may not meet proper fire and safety hazards. Because of this, the Committee directed you to submit to us a plan for renovation and modernization as well as recommendations and cost estimates.

Please summarize this and include this in the record.

Answer: The needs for modernization are described below.

The budgeting plan to meet the needs for modernization is projected over a period of nine years, primarily to meet the inherent sequential characteristics of most of the line items. However, a single year appropriation would not constitute a commitment to appropriations for succeeding years. All cost estimates provided herein are based on 1980 constant dollars. Escalation costs must be added to these estimates to obtain the budget estimate for the year in which funds are appropriated.

BUILDING 10 (CLINICAL CENTER)

This building, representing over 1,368,000 gross square feet of space, houses all the patient care and clinical research programs of the National Institutes of Health at Bethesda, and part of the basic research programs. It has been operational for over twenty-five years and increasingly is experiencing conditions of functional obsolescence. In the patient care areas, some isolated improvements have been achieved to maintain pace with advances in medical procedures and equipment; however, a substantial part of the patient care facilities are operating with nursing stations, medical support systems, and architectural and utilities systems that are obsolete.

In the research laboratory areas of the building, there has been some comprehensive upgrading of utilities systems, but additional work is required particularly with respect to significant changes in life safety codes and environmental health standards.

A corresponding architectural systems obsolescence has evolved in the public areas of the building, requiring renovations in order to achieve a level of environmental quality compatible with modern day standards and to meet the needs of the handicapped.

Under a recently completed study, over fifty individual projects of a substantive nature were identified which are necessary to bring this building up to an effective functional and environmental level. Since the building must remain operational while renovations and modernization are undertaken, a sequential program of events, to span a period of approximately four years, has been tentatively developed. The initial projects are directed at needs that must be satisfied in order to meet operational needs for medical and surgical support areas, such as Intensive Care Units; and laboratory support departments, such as Central Sterile Supply. Funds required for Building 10 renovations are estimated as follows:

	Dollars in Millions
1st year	$ 7.50
2nd year	7.50
3rd year	7.50
4th year	7.50
Total	$30.00

BUILDINGS 2, 3, 4, 5, AND 8

The original laboratory buildings constructed in the late thirties and early forties are in need of major renovation and modernization. These buildings are numbered 2, 3, 4, 5, and 8 and represent approximately 275,000 gross square feet of space. They are structurally and architecturally in sound condition; however, the interiors need to be completely reconstructed. The support systems and interior architectural features are inadequate in capacity and/or badly deteriorated. Also, modernization is required to provide for needs of the handicapped, new life safety codes, energy conservation and modern equipment requirements.

To accomplish the work, the buildings must be completely vacated and the programs moved to other suitable space. Therefore, turn-around space is needed initially to accommodate the occupants of one of the buildings. As each building is renovated, the programs of the next can be moved into the newly renovated space. The timing for completion of all buildings is estimated to be about eight to nine years. Estimated funding requirements are as follows, assuming availability of turn-around space.

	Dollars in Millions	
1st year	$ 1.00	(Design)
2nd year	9.55	(Design & Construction)
3rd year	--	
4th year	9.25	(Design & Construction)
5th year	6.10	(Construction)
6th year	0.60	(Design)
7th year	5.80	(Construction)
8th year	0.60	(Design)
9th year	5.85	(Construction)
Total	$38.75	

The alternatives for turn-around space are:

1. Relocation of programs to the Frederick Cancer Research Center, Frederick, Maryland, assuming that adequate space, now used by the National Cancer Institute research programs, conducted under contract, could be released. However, suitable space is not now available at the Frederick Cancer Research Center. Early availability of space at this location could expedite renovation.

2. Construction of a new laboratory building if funds were appropriated; however, this option would require more lead time than option 1.

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BUILDINGS 7 AND 9

The master plan for the development of the NIH Reservation, Bethesda, projects the razing of these two buildings as part of the ultimate site development. Building 7 consists of 42,900 gross square feet and was constructed in 1946. The building was designed for the purpose of providing safe working conditions for research work in infectious diseases. The design objectives were only marginally achieved when constructed, and at this time the building is totally inadequate to accommodate biohazardous work. Concern about the condition of this building was expressed in the Senate report, and it is only through extraordinary diligence on the part of the scientific personnel that safety is maintained in the studies of infectious agents carried on in this building. This problem can only be resolved in the long run by replacement of this microbiological facility by a new building specifically designed to meet safety standards for research involving infectious or biohazardous organisms.

A study completed in 1972, which was designed to develop a master plan for ultimate development and use of the building, concluded that renovation of the building for ordinary laboratory use would not be cost effective and would result in space of poor functional quality. Many of the partitions are of load-bearing wall construction and the configuration of the building limits renovation. In the short range Building 7 could be renovated to provide office and animal holding space in support of programs in adjacent buildings; however, such use would be marginally functional and in the long run, the master plan provision for razing the building is appropriate. The estimated funding needed for short-range renovations to Building 7 is three (3) million dollars.

Building 9 is a single story building with a partial basement containing about 32,000 gross square feet of space. It was constructed in 1943 for the purpose of breeding and holding animals. During the 1950's the building was marginally renovated and since then has accommodated laboratory and animal facilities. The space is functionally inadequate and not suitable for modernization. The utility and life safety support systems within the building are in need of major repair; but these repairs will not increase the quality of the facility to meet the minimal standards of the American Association for Laboratory Animal Science (AALAS) for holding animals. It is considered appropriate that this building be razed eventually, as called for in the master plan. However, at this time the utility and life support systems must be renovated to permit continued short term use of the facility. The estimated funding needed for this work is $0.25 million.

BUILDINGS 14A, B, C, D, E, F, AND G

These buildings, representing approximately 247,500 gross square feet of space, were constructed during the mid-fifties. They are used to support breeding, development and holding of small animals needed for intramural biomedical research.

In 1960 the National Institutes of Health purchased a farm near Poolesville, Maryland, containing approximately 500 acres for the purpose of breeding, developing, and holding both large and small

animals to meet the needs of the intramural research programs of the NIH. The property is named the NIH Animal Center (NIHAC). A master plan for development of the site was prepared and partially implemented. Improvements now in place at the NIHAC total approximately 200,000 gross square feet of floor space. The NIHAC master plan provided for new facilities which would replace most of the Building 14 group of buildings on the NIH Reservation. Plans and specifications for the next phase of development of the NIHAC master plan were completed in 1972. Plans provide for additional small animal facilities and utilities. However, funds have not been provided for this planned construction.

The NIH Bethesda Master Plan provides for razing of Buildings 14A through 14E with the completion of development of the NIHAC. The site is projected to be used to meet other needs. The Building 14 group is now in need of major repair and remodeling. The heating, ventilating, air conditioning and other utility systems need to be replaced and major remodeling is needed to bring the facilities to standards of the American Association of Laboratory Animal Science (AALAS).

It is now recommended that the Building 14 group of buildings be repaired and remodeled to meet minimal requirements for further short range use and that the NIHAC be further developed as originally planned.

The cost for the next phase of construction for the NIHAC is estimated to be $17.74 million.

The cost for repairing and remodeling the Building 14 group should be funded in two phases with $2.0 million needed the first year, and $3.0 million the second year.

A survey of this group of buildings is programmed during FY 1979 for the purpose of better defining the minimum needs referred to above. Hence, better estimates will be available for FY 1981.

SUMMARY

The cost of the renovations and construction described above are summarized in the following table:

SUMMARY
NIH MODERNIZATION AND RENOVATION
(dollars in millions) 1/

Building Number	1st	2nd	3rd	4th	5th	6th	7th	8th	9th	Total
10.....	$ 7.50	$ 7.50	$ 7.50	$ 7.50	$ --	$ --	$ --	$ --	$ --	$30.00
2, 3, 4, 5, & 8...	1.00	9.55	--	9.25	6.10	0.60	5.80	0.60	5.85	38.75
7.....	3.00	--	--	--	--	--	--	--	--	3.00
9.....	0.25	--	--	--	--	--	--	--	--	0.25
NIHAC 2/.....	--	--	17.74	--	--	--	--	--	--	17.74
Bldg. 14 Group....	2.00	3.00	--	--	--	--	--	--	--	5.00
Total.....	$13.75	$20.05	$25.24	$16.75	$6.10	$0.60	$5.80	$0.60	$5.85	$94.74

1/ All cost estimates are 1980 constant dollars. They must be escalated to the actual year in which funds are appropriated.

2/ National Institutes of Health Animal Center.

SUBCOMMITTEE RECESS

Senator SCHWEIKER. The subcommittee will stand in recess until 10 o'clock tomorrow morning.

[Whereupon, at 4:25 p.m., Wednesday, February 28, the subcommittee was recessed, to reconvene at 10 a.m., Thursday, March 1.]

DEPARTMENTS OF LABOR AND HEALTH, EDUCATION, AND WELFARE AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 1980

THURSDAY, MARCH 1, 1979

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
Washington, D.C.

The subcommittee met at 10:05 a.m. in room S-128 of the Capitol, Senator Mark O. Hatfield presiding.

Present: Senators Burdick and Hatfield.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

NATIONAL INSTITUTES OF HEALTH

NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

STATEMENT OF DR. NORMAN KRETCHMER, DIRECTOR

FUNDING FOR HEALTH RESEARCH PROGRAMS

Senator HATFIELD. The subcommittee will come to order. Today we will continue hearing testimony from Dr. Fredrickson and other distinguished leaders in the National Institutes of Health.

I might say that as a new member of the subcommittee, this is a special opportunity for me to welcome the education that you will give me.

Senators Magnuson and Schweiker said earlier perhaps one of the most difficult tasks before this committee is to determine adequate and appropriate levels of funding for the Nation's health research programs.

There are emergent needs in all areas, and we, along with your counsel, must assess the capacities.

While the Appropriation's Committee often defers to your collective expertise, we, too, bring to these meetings our individual and specific areas of interest, and I will indicate my own particular special areas of interest as we go along, mostly in the area of nutrition and central nervous system regeneration.

I think this morning we will start with Dr. Norman Kretchmer, the Director of the National Institute of Child Health and Human Development, and ask him to present his testimony.

We have here a full printed statement, which will be placed in the record, and you may handle your testimony as you wish, in summarizing, or highlighting it, however you wish to proceed.

[The statement follows:]

STATEMENT OF DR. NORMAN KRETCHMER

Mr. Chairman and members of the Committee:

The National Institute of Child Health and Human Development, one of the 11 National Institutes of Health, sponsors biomedical and behavioral research on the earliest periods of life, from conception through birth and childhood. This work is founded on the premise that adult health and well-being are determined to a great extent by events that occur very early in life--in childhood and infancy, before birth, and even before conception.

The Institute's goals are:

- To assure the birth of healthy babies;
- To assure the birth of wanted babies;
- To provide all children the chance for a productive and healthy adulthood.

To accomplish these aims, the NICHD sponsors a combination of biomedical and behavioral research in the reproductive and the developmental sciences. Reproductive studies range from research on the development of sperm and egg cells to studies of population and family dynamics; research in the developmental sciences covers subjects ranging from human embryology to childhood learning and social development. Much of this work is basic research, because the development of fundamental knowledge about reproductive and developmental biology and early behavior is the key to preventing the biologic onset of disease or the emergence of behavioral problems. In examining the earliest stages of life, NICHD-sponsored scientists are seeking early opportunities to prevent diseases, disorders, and social and psychological handicaps that can affect people any time in their lives.

In Fiscal Year 1980, the Institute expects to continue support of areas in which substantial progress is being made, maintaining the same program level as in 1979. Two main areas of research concentration will be human reproduction and the special problems of the pregnant woman, fetus, and newborn infant. I would like to give you some examples of NICHD-sponsored research in these areas, and then discuss certain basic studies that promise to solve problems in both fields.

ADVANCES IN THE REPRODUCTIVE SCIENCES

NICHD-supported research in the reproductive sciences continues to yield data of potential significance. The goal of this effort is to enable people with different needs to have the number of children they want at the time these babies are wanted--to regulate fertility and to overcome infertility.

In the search for new contraceptives, the most promising development concerns a group of drugs that resemble a naturally-occurring hormone called luteinizing hormone releasing factor. In preliminary studies on animals and human females, some of these drugs blocked ovulation when administered on a daily, continuous basis; they may inhibit fertility in males as well. In 1980, the Institute plans to test these compounds in clinical trials involving both men and women.

In a significant advance in natural family planning, findings from a large NICHD-supported clinical trial in the Los Angeles area show that periodic abstinence is most effective when several indicators

are used in conjunction to determine the woman's fertile period. Couples had a significantly higher success rate using the sympto-thermal method, in which a woman keeps track of several body signs, including changes in temperature and in consistency of cervical mucus, to tell when ovulation takes place. In the less effective method, consistency of cervical mucus is the only measure used to judge when ovulation is occurring.

Along with efforts to develop new contraceptives for both men and women, NICHD-supported scientists will continue to assess the safety of methods now in use. Animal studies have revealed a number of possible adverse effects of vasectomy, including an increase in the severity of diet-induced arterial disease. Research will continue on the possible health hazards of oral contraceptives for women; in recent studies, the Pill has been associated with an increased risk of stroke, especially in women who smoke.

The NICHD plans to support studies on how children's cognitive and social learning is affected by changes in the structure of the American family, especially by family instability and teenage parenthood. Such studies will yield basic knowledge about early development that might apply to the management of some types of socially-caused mental retardation and to treatment of learning disabilities.

RESEARCH IN PREGNANCY AND INFANCY

Conditions in pregnancy that adversely affect the fetus will continue to receive major attention. Institute-supported scientists are looking at the effects of maternal infections, metabolic disorders, and environmental agents such as pollutants, alcohol, and foods on the fetus and infant.

Diabetes in pregnancy, a disorder that results in birth defects, fetal metabolic disorders and other serious problems, is the focus of four Major Research Programs supported by the Institute. These programs, initiated in FY 1978 at the direction of the Congress, are large, multi-disciplinary, targeted studies of specific health problems affecting pregnant women and their infants. In a fifth Major Research Program, scientists are working to prevent premature birth--a prime factor in infant illnesses and deaths--by investigating what factors trigger labor. A sixth Program is focusing on the origins of the Sudden Infant Death Syndrome (SIDS).

SIDS will continue to be a major focus of Institute activities in 1980. Contributing to growing evidence that SIDS victims were not healthy before death, pathologists have found abnormalities in the brain stems of crib death victims, a neurologic defect that could be an important indicator of babies at risk for SIDS. Other indices of risk are expected to come from the Institute's large epidemiological study of SIDS victims and control infants. These warning signs may be used to identify susceptible infants as early as the first month of life.

The Institute has completed a study, requested by Congress, on the possibility of establishing a clinical research center for pregnancy and infancy studies. This center could be a coordinating point for the Major Research Program grants and for a nationwide network of scientists working on perinatal health problems. Better communication between government scientists and university-based investigators will accelerate progress in the effort to prevent conditions in perinatal life that lead to sudden infant death, mental retardation, birth defects, and many other developmental problems.

BASIC RESEARCH

Through fundamental research on biological and behavioral processes, the NICHD is building a reservoir of knowledge that will apply across the spectrum of problems in reproduction, pregnancy, infancy, childhood and adolescence. For example, new NICHD studies on how health habits develop in childhood are expected to provide valuable clues on how to prevent overeating and smoking in childhood, and unwanted pregnancy among adolescents. This work, started with funds appropriated in 1979, has been broadened to encompass studies of a range of habits harmful to health in later life.

Some of the most exciting recent advances have been made in the field of molecular biology. Working with recombinant DNA techniques, an NICHD scientist and an Institute grantee have succeeded in removing single genes from the cells of mammals and making billions of copies of these naturally-occurring genes for study in the laboratory. These techniques have opened the door to direct study of genetic "mistakes" that may be responsible for blood disorders called thalassemias and for many other genetic disorders. Knowledge of how such errors occur may someday enable scientists to prevent certain genetic diseases. The new techniques for copying and examining single genes are also relevant to reproductive medicine: as scientists learn more about how certain genes control reproductive functions, this knowledge can be applied to the treatment of infertility and to contraception.

Another area of basic research spanning the range of reproduction and development is nutrition. In FY 1980 the Institute will begin new studies on the components of human milk, how the newborn's body processes these nutrients, how human milk acts to make the infant immune to some infections, and how the composition of milk varies among individual mothers. A program begun last year to distinguish the early cultural and behavioral determinants of eating habits should produce useful data for the treatment of overweight and other nutritional disorders that have a behavioral component. Findings from basic research on the relationship between nutrition and certain aspects of reproduction--fertility, infertility, the development of sperm and egg cells, the age at which puberty begins, and infertility during breast feeding--also have clear clinical relevance.

CONCLUSION

In this statement I have described recent research advances from NICHD-supported studies and discussed a few areas for major commitment in Fiscal Year 1980. The problems investigated in NICHD programs are of vast complexity, and solutions will come not from single areas but from an ongoing accumulation of fundamental knowledge about the processes of reproduction, pregnancy, infancy and childhood. The more we know about these processes, the more successful we will be in preventing disease and disability at an early stage, before such conditions become serious handicaps requiring vast amounts of money for treatment and care.

Mr. Chairman, the NICHD requests $204,381,000 for FY 1980. In addition, we are requesting a supplemental appropriation of $10,713,000 to increase the 1979 funding for the population research program. These funds, initially identified in the FY 1979 President's Budget, would be used to support new research related to the initiative on adolescent health and the prevention of unwanted pregnancy. They would also permit expansion of research in other areas of the population sciences with special emphasis on the development and evaluation of methods for regulating male fertility and improving the safety of oral contraceptives for women. I would be glad to answer questions and to supply additional information for the record.

MISSION OF NICHD

Dr. KRETCHMER. Mr. Chairman, I would like to submit the complete statement for the record and summarize our ideas and goals very briefly.

I would like to indicate that the National Institute of Child Health and Human Development is somewhat different from the Institutes that preceded it, in the sense that our mission is not related to any particular disease or disability. Rather the NICHD should be considered a noncategorical Institute, interested in many of the things that take place during human development, especially those in early life.

The Institute's goals are, through research, to assure the birth of healthy babies, to assure the birth of wanted babies, and to provide all children the opportunity for a productive and healthy adult life.

To accomplish these goals, the NICHD supports a combination of biomedical and behavioral research in the reproductive and developmental sciences.

Much of this work can be considered basic research, because the development of fundamental knowledge in the areas of reproduction, developmental biology, and early behavior is really the key to preventing many diseases and disabilities that will be encountered throughout life.

The goal in reproductive sciences is to enable people with different needs to have the number of children they want at the time that these babies are wanted, in other words, to regulate fertility and overcome infertility.

The NICHD is responsible for research on new contraceptives. The most promising new development is the use of a naturally occurring hormone, produced by a specific part of the brain, which might be utilized as a contraceptive agent, for both men and women.

We have been interested in and have concentrated on the safety of the various contraceptive methods that are in use, and our research will continue to focus on the health hazards of oral contraceptives. For example, research has shown that the pill is associated with an increased risk of stroke, particularly for women who smoke and more particularly for women above the age of 35.

The other major program of the Institute is concerned with research in the areas related to pregnancy, infancy, and early childhood.

We have recently funded six major research programs. The focus of four of these programs is diabetes and pregnancy as associated with a variety of birth defects, and fetal metabolic disorders.

A fifth major research program concentrates on the prevention of premature birth. A sixth is concentrating on problems of Sudden Infant Death Syndrome.

The Institute has just completed a study which was requested by the Congress on the possibility of establishing an off-campus Federal clinical research facility for research on pregnancy and infancy.

We have several new initiatives. In the area of the development of health habits and attitudes, we are interested in how children develop habits in the area of nutrition, and how to prevent harmful health behavior, such as smoking.

Problems investigated through the NICHD are broad and relate predominately to the prevention of disease and disability. The more we know about normal processes, the more successful we will be in preventing disease and disability at the earliest stages in life, when it really counts.

Mr. Chairman, the National Institute of Child Health and Human Development requests $204,381,000 for fiscal year 1980.

In addition, we are requesting a supplemental appropriation of $10,713,000 to increase the fiscal year 1979 funding for population research.

I would be glad to answer any questions.

Thank you.

SUPPLEMENTAL REQUEST

Senator HATFIELD. Thank you very much, Dr. Kretchmer.

The Secretary indicated that one of the higher priorities is in the area of the Center for Population Research.

You also have a 1979 supplemental, I believe, as well as, in the President's budget for 1980. Could you describe what your plans are for the Center for Population Research, and what you intend to do with the additional amounts specifically as provided in the supplemental?

Dr. KRETCHMER. The additional amount, which is $10,713,000, will be used primarily for research in reproductive biology.

Some of the money will be used to increase research activities in the social and behavioral aspects of population, which is so important to the field, and to continue the work in contraceptive development and safety.

Senator HATFIELD. If the supplemental did not become law, say, until later in the year, July or August, what would be the impact on the terms of your ability to really spend this additional $10 million?

Dr. KRETCHMER. We have a fair backlog of research, so that it would be merely an administrative problem to spend it.

But it could be done.

USE OF PRIMATE CENTERS

Senator HATFIELD. Do you utilize the primate centers in your work?

Dr. KRETCHMER. Yes.

Senator HATFIELD. Is that basically the rhesus now?

Dr. KRETCHMER. It is basically the rhesus monkey, although we are using the larger monkeys also. We've been involved in the primate colony in Oregon and we have been involved in the primate colony in Davis, Calif.

Studies of the subhuman primates are incredibly important.

ADOLESCENT PREGNANCY

Senator HATFIELD. We are told that there will be in excess of 1½ million births to adolescent women in the United States, and there is, as I see a new $60 million program in the Office of the Assistant Secretary, just related to the subject of adolescent pregnancy.

Can you tell me a little bit about this program and how your Institute relates to it?

Dr. KRETCHMER. Yes. Our Institute relates to the research portion of the DHEW initiative in adolescent pregnancy.

We are pursuing studies of the younger adolescents, the very young women at the ages of 12 and 13, who are considered at high risk in terms of their pregnancy.

Another aspect that we are investigating with a great deal of vigor is the question of what is the best approach to contraceptive agents for teenagers.

Some of the approaches to birth control that we now have are not really adaptable or useful for teenagers.

As I mentioned before, the program in the social and behavioral sciences is important, and relates to risk-taking behavior and the use of contraceptives.

ORAL CONTRACEPTIVES

Senator HATFIELD. Dr. Kretchmer, you mentioned awhile ago about the publicity given to certain side effects from oral contraceptives.

Has there been a specific decline in any age group, as far as we can tell in the matter of using the pill?

Dr. KRETCHMER. The pool of pill users is so great that declines are not easy to discern. Warnings have gone out through the press, nationwide, and as a matter of fact, throughout the world.

I think women who are smoking and taking the pill really are quite conscious of the problems.

Now, in terms of the decline, I can't offhand, provide the exact information for you, but I could provide it for the record.

Senator HATFIELD. Would you do that; please?

[The information follows:]

Oral contraceptive use among women in the United States increased steadily from 1960 to 1973. In 1976, the proportion of currently married women aged 15–44 years who were using oral contraceptives was estimated to be 2.8 percent less than for 1973 (22.3 percent versus 25.1 percent). The relationship between oral contraceptive use and an increased risk for heart attacks was widely publicized in 1975.

These considerations suggest that some women stopped using oral contraceptives because of adverse publicity. However, there was a concomitant increase (1976 versus 1973) in the percentage of currently married women who were protected from unwanted pregnancy by surgical sterilization (male and female). Thus, the proportion of currently married women who were pregnant, post-partum, seeking pregnancy, or unprotected and not seeking pregnancy was 28.2 percent for 1976 and 28.5 percent for 1973, virtually unchanged.

PROGRAM PRIORITIES

Senator HATFIELD. As you noted in yesterday's hearing, various directors were asked a question relating to priorities of programs, and what they represented, in a numerical figure.

Could you list for us, now or for the record, what you consider your highest priority programs, what those costs are cumulatively, and what you would consider as the lesser of the priorities, and what those costs represent.

In case there is a call for reducing or cutting the budget, this committee would like to be able to do so with some kind of scalpel approach, rather than meat ax.

That is why we need that kind of information.

Dr. KRETCHMER. Do you want me to comment on it now or for the record?

Senator HATFIELD. You may wish to do it now or both.

Dr. KRETCHMER. Just a quick comment now, and we will provide more information for the record.

In terms of mechanism, we are most concerned about direct support through research grants.

Consequently, if we were forced to cut back, we would protect individual research grants above all.

In terms of program emphasis, we are most concerned with areas that we consider would pay off in prevention of disease and disability.

For example, the area of high-risk pregnancy would be one of our top priorities. Additionally, I would consider reproductive biology, and the events of reproduction of high priority because here new knowledge will lead to the prevention of a great deal of problems in society.

I will stop there and then provide more for the record.

[The information follows:]

Programs of highest priority

	Cost
High risk pregnancy, including studies on pregnancy in the adolescent, and research on the relationship of diabetes during pregnancy to birth defects and metabolic disorders of the fetus	$26,656,000
Fertility/infertility, where fundamental studies in basic reproductive biology include the role of hormones in fertilization and implantation; human infertility; processes of male and female reproduction, and the role of the brain in reproduction	48,549,000
Nutrition, with emphasis on nutritional antecedents of disease in infancy, childhood and adulthood	21,725,000
Mental retardation, which includes an expanded research effort in Down's syndrome (mongolism), with particular attention to its genetic aspects	31,258,000
Sudden infant death syndrome (SIDS), where we now know that SIDS babies were not normal babies before they died. Continued data analysis will provide indices to permit identification of infants at risk for SIDS	10,500,000
Total	138,688,000

Programs of lowest priority

Selected contract programs in research for mothers and children and in population research	3,141,000
Center grant programs	2,450,000
Selected parts of research project grants, mostly noncompeting and administrative supplements	2,821,000
Equipment and renovation projects in the intramural research program	800,000
Selected administrative and management functions	1,007,000
Total	10,219,000

INFANT MORTALITY

Senator HATFIELD. Both program and dollar figures.

Dr. Kretchmer, one of the things that has really caught my attention over the years is the subject of infant mortality.

I am concerned whether we are addressing this, and why our rates have been as high as they have been.

I'm delighted to see from the report that the Assistant Secretary for Health relating to preventive health programs in this country has stated that one of the goals is to reduce that mortality from 12 per 100,000.

Would you care to comment on what your role is in this Institute toward achieving that goal, and why we have this particular rate?

Dr. KRETCHMER. Our role is related to both infant mortality and morbidity.

I might say that Washington, D.C., has the highest infant mortality rate in the United States.

Senator HATFIELD. What is that rate?

Dr. KRETCHMER. Twenty-six per thousand.

Senator HATFIELD. Twenty-six?

Dr. KRETCHMER. Yes.

Senator HATFIELD. Per thousand?

Dr. KRETCHMER. Live births.

Senator HATFIELD. I said 12 per 100,000. That should be 12 per 1,000.

Dr. KRETCHMER. Fifteen is our figure; fourteen point something.

Senator HATFIELD. Per thousand?

Dr. KRETCHMER. Yes; live births.

Senator HATFIELD. The Assistant Secretary, I'm told, gave us these figures of 12 per 100,000.

Dr. KRETCHMER. That must be for total population. It is not the usual way that pediatricians think of it.

Senator HATFIELD. Let's keep it in the realm of pediatricians.

Dr. KRETCHMER. At any rate, without going into figures, Washington, D.C., has the highest rate in the United States; Mayor Barry has been aware of this, and has appointed a special committee to examine the problem.

Infant mortality is a large problem. Infant morbidity becomes an even larger problem, because you are involved with a lifetime of—not disease, but potentially a lifetime of disability and an unpleasant quality of life.

So, this Institute tries to concentrate on these problems as early as possible, prior to fertilization, in the early stages of fetal development, and certainly in early infancy.

One of the prime factors is that some babies are born too early, before they have had a chance to mature in utero.

These are areas of great concentration.

Senator HATFIELD. That is very shocking to know about our Nation's Capital, isn't it?

Dr. KRETCHMER. I left out one response. The difference between Sweden and the United States is that we are really a very heterogeneous country, and Sweden is homogeneous, almost, genetically. We have had heterogeneity not only culturally and genetically, but also socioeconomically.

If you examine socioeconomics relative to infant mortality and morbidity, you will find a lower socioeconomic status correlated with a higher rate of infant mortality.

INFANT MORTALITY PROBLEM IN WASHINGTON, D.C.

Senator HATFIELD. Have you any comments on special programs, or how are you dealing with this unique situation in Washington?

Dr. KRETCHMER. We have offered consultation to the three universities in Washington, D.C., and met on a number of occasions with representatives of Howard, Georgetown and George Washington Universities.

In addition, we have indicated to the Mayor that we are available. We do have an association with one of the representatives on his committee, Dr. Fredrick Green.

On a national basis, we have established, with the advice of the Congress, a network of perinatal research centers.

We now have six of these major research programs in place, four of them concentrating on perinatal research, one on sudden infant death, and one on the beginnings of labor—on the mechanism of birth.

Senator HATFIELD. Do I understand that you are telling me that there is not a defined cause that has been determined for this higher rate in the district, and that a bit of research must precede a program of attack?

Dr. KRETCHMER. Research is necessary. Socioeconomic status is a factor.

Senator HATFIELD. Does that then call for a nonmedical solution?

Dr. KRETCHMER. Frankly, Mr. Chairman, I think that a good deal of the problem calls for a nonmedical solution. But I think that they have to go hand in hand, medical and nonmedical.

Senator HATFIELD. Could you, for the record, provide us with sort of a one, two, three definition as to the causes of this higher infant mortality in the district, and sort of a one, two, three program of attack?

Dr. KRETCHMER. I would be glad to.

[The information follows:]

Washington, D.C., ranks No. 1 in infant mortality in the Nation. Approximately 27.3 out of every 1,000 infants die in the first year of life in this city, compared to 13.5 per 1,000 in the State of Maryland. These deaths can be attributed to multiple, interacting conditions that affect the newborn's chances for survival. Poor housing and living conditions, lack of adequate social and medical services, and lack of opportunity for gainful employment are the major variables that affect infant mortality in any area, including the District of Columbia.

It has been documented (Birch, 1970) that age, parity, growth, diet, and obstetrical care contribute to a woman's reproductive performance. Lack of appropriate resources to insure proper health care and nutrition during the prenatal and perinatal period increases the probability of infant morbidity and mortality. Hazardous housing conditions increase the risk of injuries and accidents. Consequently, women of childbearing age who live in the District of Columbia and suffer from poverty are at greater risk for complications of pregnancy.

For children born to adolescent mothers, the chances for neonatal survival are comprised further. Among adolescents the prevalence of high risk pregnancy (hypertensive and toxemic pregnancy) increases fivefold and substantially raises the likelihood of prematurity, low birthweight, and infant death. Accordingly, the high rate of adolescent pregnancy in the District of Columbia viewed in retrospect has serious consequences for infant morbidity and mortality.

Successful efforts to reduce infant mortality rates in other regions have involved a combination of educational, health, social, and economic strategies. Realistic, interesting, and informative educational programs have been instituted in elementary and secondary schools and neighborhood facilities to increase knowledge of

proper nutrition, health care, and parenting. Local colleges, universities and health training institutions have been utilized to assist targeted neighborhood schools and community groups in planning and implementing the training. Widespread public education campaigns involving the media (radio, television) have been used to augment the training process. Programs to increase the availability of attractive, low-cost medical services for both prenatal and infant care have proved effective. A cadre of trained nurse practitioners, midwives, and allied health personnel have been used in these clinics. In addition, supplementary social service programs in family planning and consumer awareness have been useful to expand knowledge of choices and improve decisionmaking about living conditions and child bearing.

Nonmedical factors have also played an important role in reducing infant mortality. Examples include employment programs and job-related training to help improve standards of living, and large-scale urban renewal projects to eradicate hazardous, unhealthy living conditions.

Any plan of attack on a health problem of this magnitude should include a health care research and evaluation component to determine the best methodologies for effective health care delivery. Basic biomedical and behavioral research on the management of complications of pregnancy, and the prevention of unwanted adolescent pregnancy should be instituted as well.

By utilizing a multifaceted approach to prevent and remediate impoverished conditions, the likelihood of lowering infant mortality in Washington, D.C., can be substantially increased.

MENTAL RETARDATION

Senator HATFIELD. I would like to shift to the mental retardation program.

Are you familiar with the article written by Dr. Zigler?

Dr. KRETCHMER. Yes, I'm very familiar with that article.

Senator HATFIELD. You, of course, are aware that his thesis is one of the greatest works done in the early 1970's, as it relates to research on mental retardation.

Can we make a judgment on the article, and in so doing would you comment on the current status of the studies of mental retardation? Are they being neglected, for instance? Are these criticisms valid?

Also, I believe in the article there was a reference made by Dr. Zigler to a new disciplinary group of senior research workers who met under the auspices of the Association of Medical Deficiency.

Are you aware of such a meeting? And give us any background that you have.

Dr. KRETCHMER. I'm very aware of Dr. Zigler's article, and as a matter of fact, in the next month or so, there will be a letter from me to the editor, which is in the form of a commentary and a rebuttal to Dr. Zigler's article.

Dr. Zigler maintained, as you indicate, Senator, that the Institute has been lacking in its efforts in the area of mental retardation.

I would take issue with this. I have been in the Institute for the past 5 years, and at the present time we spend approximately $31 million in the area of mental retardation.

We have 12 mental retardation centers placed in the United States. Over the past 5 years their core moneys have increased from $5.6 million to approximately $7 million.

The issues that Dr. Zigler brought up in terms of how mental retardation activities have been going on within the U. S. Government has fascinated me. One of the first official acts I initiated in taking office was to establish with the then Director of the National Institute of Mental Health a committee of experts; and on that

committee were Dr. Zigler and the present Assistant Secretary for Health Dr. Julius Richmond.

At the time Dr. Richmond was professor of pediatrics and public health at Harvard. Dr. George Tarjan from UCLA was the chairman. There were five or six people on the committee.

They wrote a report, which was made public, about what both Institutes should do to improve the program. These consultants helped us a great deal. But meanwhile, this program has been going steadily.

The issue, I think, hinges on a few words. The issue is what is considered research, and what is considered service. The issue is also how money is calculated in terms of our activities in mental retardation.

And if you look at the money—and I will provide the increases for the record, if you like, or even a summary of the report, or the letter that I wrote—we are now up to about $31 million in research money, which constitutes a big percentage of our total research money.

Our total funding for mothers and children is $118 million. So a substantial portion of our budget is in mental retardation.

The research in high risk pregnancy also relates to mental retardation, but Dr. Zigler doesn't accept that.

I would be delighted to submit a summary of that letter.

Senator HATFIELD. Could you send a copy of the letter to the committee?

Dr. KRETCHMER. I would be delighted. I better include, also, a copy of Dr. Zigler's paper.

[The letter was submitted and inserted in the subcommittee files, and the information follows:]

NICHD Support of the Behavioral Sciences

Norman Kretchmer, M.D., Ph.D.

The National Institute of Child Health and Human Development

"National Crisis in Mental Retardation Research" (Zigler 1978) was highly critical of the NICHD policy, particularly in regard to its program of support for the behavioral sciences and mental retardation research. In response, I would like to describe two pertinent aspects of the NIH and NICHD operations and then comment on the specific issues raised.

Background

First, fundamental to any discussion of support of research by the NICHD is an understanding of the NIH peer review system. Research applications are directed to the Division of Research Grants, an autonomous unit of the NIH responsible for evaluating research proposals for scientific merit. After review by study sections, grant applications are referred for a second review to the National Advisory Council of the appropriate Institute, whose members, both scientists and lay persons, have been appointed by the Secretary of the DHEW. The Institute Director plays no part in judging scientific merit, or recommending approval or disapproval of applications for grants. In the case of the NICHD, the record shows that once research proposals in the behavioral sciences and mental retardation pass scientific merit review, the percentage of them funded is nearly the same as for proposals in other fields. Thus, the success of the mental retardation research endeavor depends not on the degree of personal support it receives from the Institute Director but on the ability of the research community to compete for available research funds.

Second, it is important to point out that the Mental Retardation and Developmental Disabilities Branch (MRDD) of the Institute is not the sole source within the NICHD for support of mental retardation and the behavioral sciences. In Fiscal Year 1977 the MRDD funded mental retardation research, both biomedical and behavioral, at $23,349,000, while the NICHD total for such research was $29,188,000, a difference of $5,839,000. This last figure is a composite of activities of other branches within the NICHD. Total extramural support for all behavioral sciences research for Fiscal Year 1977 by both the Center for Research for Mothers and Children and the Center for Population Research was $25,056,000.

Funding Trends Over Time

Turning to Dr. Zigler's statements on NICHD funding, I would point out that they embrace only a narrow time frame and do not reflect some significant longer term trends.

1. Dr. Zigler stated that in recent years, research in the biomedical area, and perinatal biology in particular, has expanded more than research in mental retardation. He cited budget increments for these programs from 1974 to 1976. Table 1 shows the budget for the MRDD and the Growth

and Development Branch (now the Developmental Biology and Nutrition Branch and the Human Learning and Behavior Branch) during two periods, 1971 to 1975 and 1975 to 1979.

Table 1. NICHD Budget, Mental Retardation and Developmental Disabilities Branch (MRDD), Growth and Development Branch (G & D), 1971-1975 and 1975-1979

Program	1971	1975	% Increase 1971-75	1979	% Increase 1975-79
MRDD	14,126	20,528	45.3	28,134	37.1
G & D	16,969	19,595	15.5	31,497	60.7

Dollars in thousands

The Growth and Development program has expanded more rapidly than the Mental Retardation program since 1975, although a 37 percent increase in funds for the latter in 4 years is certainly significant. A number of reasons account for the differential in growth rate. Most important among these are the Congressional and Secretarial mandates to develop research programs in specific areas, such as the Major Research Programs that focus on perinatal research, diabetes, nutrition, teenage pregnancy, and smoking. Much of the research in these areas has a clear and often direct relationship to mental retardation.

2. Dr. Zigler stated that since 1974 the behavioral sciences have not been strongly supported and that expansion has occurred primarily in the biomedical area. Table 2 shows funding trends since 1972 for biomedical and behavioral research in programs of the Institute's Center for Research for Mothers and Children (CRMC).

Table 2. NICHD Funding Trends, Biomedical and Behavioral Research, 1972-1977

Program	1972	1973	1974	1975	1976	1977
% Biomedical	72.8	75.7	76.4	77.5	75.4	76.8
% Behavioral	27.2	24.3	23.6	22.5	24.6	23.2

Clearly, there is no indication of a major shift in funds.

3. To support his claim that the NICHD has deemphasized the behavioral sciences, Dr. Zigler stated that in early 1977 only 11 percent of funds requested in the behavioral sciences were awarded by the CRMC, compared to 30 percent of those requested for the biomedical sciences. The correct figures, based on the actions taken by the National Advisory Council, January 1977, are shown in Table 3.

Table 3. Center for Research for Mothers and Children (CRMC) Awards to Behavioral and Biomedical Sciences, 1977 (percentage of funds requested)

Program	Requested Biomed.	Requested Behav.	% Approved Biomed.	% Approved Behav.	% of Approved Funded Biomed.	% of Approved Funded Behav.	% of Requested Funded Biomed.	% of Requested Funded Behav.
CRMC Total	$12,405	$2,847	55.7	43.8	40.6	31.9	22.6	13.9
MRDD Branch	$ 2,632	$ 772	56.0	58.5	27.4	46.9	15.4	27.5

Dollars in thousands

These figures show that behavioral applications in mental retardation fared well. The figures for the full year of 1976 also refute a claim of diminishing support for behavioral research. For the CRMC, 59.8 percent of biomedical and 63.3 percent of behavioral applications that were approved were funded; corresponding figures for the MRDD were 70.8 percent and 76.7 percent, respectively.

4. Dr. Zigler stated that funding for the 12 Mental Retardation Research Centers, in terms of real purchasing power, is 50 percent of that of 7 years ago. The correct figures are shown in Table 4.

Table 4. Budgets for Mental Retardation Research Centers (MRRC), 1971 and 1978

Program	1971 Budget	1978 Budget	1978 Budget in Constant 1971 Dollars	% of 1971 Dollars
MRRC	$4,636	$6,208	$3,836	82.7

Dollars in thousands

5. Dr. Zigler stated that out of the NIH budget of nearly $3 billion for 1979, only 1.6 percent of the funds support behavioral research. The correct figures for the NIH and the NICHD can be seen in Table 5.

Table 5. Behavioral Research Support by NIH and NICHD, 1979 (percentage of budget)

	1979 Presidential Budget	Behavioral Research
NIH (1979)	$2,884,720	$70,168 (2.4%)
NICHD (1979	$ 198,931	$35,977 (18.1%)

Dollars in thousands

NICHD Mission in Mental Retardation

In his article, Dr. Zigler refers to the "primitive state" of our knowledge of cultural-familial retardation, and of the need for good behavioral and interdisciplinary research in this area, supported by a more complete understanding of normal development. I agree with him. But I cannot agree that there is a "crisis in mental retardation research." The NIH and the NICHD have always welcomed and will continue to support exciting ideas and well-conceived research approaches in mental retardation.

Dr. Zigler quite properly attributes the realization of advances in mental retardation research to the establishment of the NICHD. Much of the work he cited, and many other achievements, were supported by NICHD funds. As its Director, I am committed to the concept that has guided the NICHD since its creation: a broadly based Institute focusing on human growth and development and on mental retardation as an integral part of that investigation. I believe that this concept is active, that the focus remains as broad as ever, that the developmental approach continues to be the primary emphasis, and that mental retardation research remains strong and well supported.

In keeping with this concept, some mental retardation research is conducted in the context of other programs within the Institute, in human learning, behavior, developmental biology, nutrition and perinatal biology, with the MRDD available for input. Indeed, it is this concept that argues most strongly against establishing either a separate institute or a center for mental retardation.

Staff Appointments

The dearth of behavioral scientists at high administrative levels in the Institute is a legitimate concern. I have begun to remedy the situation by designating a psychologist with extensive administrative experience for a senior position on my staff. I plan to recruit other behavioral scientists for line positions where they can exercise program management. The creation of a position of Associate Director for Behavioral Sciences would not serve this end. I should point out that a shortage of behavioral scientists in high positions is not a measure of the input by these specialists in formulating policy. The NICHD relies heavily on the advice of its behavioral scientists as well as the contributions of Council members and consultants from behavioral disciplines.

The original Council appointed to advise the Institute in 1964 included seven persons "representing" mental retardation and the behavioral sciences among its 15 members. The present Council of 17 members has six representatives of these interests plus a teacher of the deaf. As for the MRDD, it is staffed by three full-time professionals--as is the Developmental Biology and Nutrition Branch and the Human Learning and Behavior Branch, and also the Pregnancy and Infancy Branch. There are 23 behavioral/social scientists, at the doctoral level, within the Institute, ten in the intramural program and 13 in the extramural program. The NICHD has a total of 158 staff members who are either M.D.'s or Ph.D.'s.

Study Section Review of Mental Retardation Grants

Finally requiring comment are Dr. Zigler's statements on the scientific review of applications for behavioral science research in mental retardation. Members of the Developmental Behavioral Sciences Study Section (now called the Human Development Study Section) are prominent investigators in the field, not subject to NIH and DHEW influence. The group might reasonably be expected to have a bias in favor of approving the maximum number of proposals in the field. The fact that they do, indeed, approve a smaller percentage of proposals than many other study sections speaks to the quality and impartiality of their review. The problem lies not with the members but with the scientific merit of the proposals submitted. The group tends to disapprove weak proposals rather than approve them with priority scores too low to merit funds. The claim that this study section votes an atypical pattern of merit scores, and that the normalization process further reduces chances for funding, is incorrect. Normalization is an aid to averaging, not a hindrance. The need is for more high-quality research applications, not a change in membership or procedures of the study section.

Research Priorities

The NICHD is as concerned as Dr. Zigler about avoiding a schism between biomedical and behavioral research. We agree that interaction between the two is an important ingredient for further progress in research on mental retardation and human development. Some of the areas Dr. Zigler cited as requiring major research are the very ones into which the NICHD is moving. For example, a major part of our research effort in teenage pregnancy involves the support of behavioral studies. What Dr. Zigler overlooked is that such studies might appear under the behavioral sciences program of the Center for Population Research (CPR), which can oversee them more adequately than the MRDD. The Institute is not prepared, however, to fund demonstrations of social practices and educational techniques involving the retarded, which Dr. Zigler lists among his priorities. These are not consistent with the mission of the NICHD and are thus the province of other agencies.

REFERENCE

Zigler, Edward. National Crisis in Mental Retardation Research. American Journal of Mental Deficiency, 83:1, 1978.

Editor's Note

The Editor invited Dr. Zigler to contribute this guest editorial in response to a significant decline in support of research on mental retardation and of behavior science generally and in light of the author's experience both in research and in government. A leading behavioral scientist in mental retardation and in child development, Dr Zigler is former Director of the Office of Child Development.

National Crisis in Mental Retardation Research

EDWARD ZIGLER
Yale University

The incidence of mental retardation will be significantly reduced only when we have a greater understanding of the nonorganic form of mental retardation, the type that afflicts approximately 75 percent of persons labeled mentally retarded. Such an understanding requires an interdisciplinary research effort that includes a major contribution from the behavior sciences. The current level of support of mental retardation and behavior science research by the National Institute of Child Health and Human Development limits the nation's capability of achieving the goals of preventing and ameliorating mental retardation.

In her address to the recent convention of the National Association for Retarded Citizens (NARC), Rosalynn Carter (Note 1) voiced her commitment to do all she can to improve the quality of the lives of America's retarded citizens. Mrs. Carter's commitment is an asset not only to retarded persons and their families but to all workers concerned with preventing and ameliorating the condition of mental retardation. Indeed, Washington sources agree that Mrs. Carter has been instrumental in gaining the budgetary increase proposed for the National Institute of Child Health and Human Development (NICHD) in the coming fiscal year ("Federal Budget Increases," 1978). This institute is the major source of funding for research in the area of mental retardation. It is unfortunate, however, that in an otherwise excellent speech, Mrs. Carter perpetuated a myth by stating: "We know that if all existing medical and scientific knowledge were applied right now, the incidence of mental retardation could be reduced by half" (p. 4). This view, which continues to be promoted by the President's Committee on Mental Retardation (1972, Note 2), was recently shown by Clarke and Clarke (1977) to be overly optimistic and erroneous.

The scientific community has made great advances in understanding mental retardation and in developing the technology to prevent and ameliorate this condition. Excellent reviews of the progress already made have been written by Begab (1974) and Clarke and Clarke (1977); however, these investigators make it clear that the scientific advances made in recent decades have been much more related to the smaller number of cases of retardation due to organic pathology than to the approximately 75 percent of cases having no known organic cause. Retarded persons who have an organic dysfunction are generally severely or profoundly retarded, with IQs well below 50. Those without known organic cause, also known as cultural-familially retarded, typically have IQs above 50. If we used every technique that scientific research has indicated is effective in reducing the incidence of mental retardation (e.g., genetic counseling, amniocentesis, prenatal and neonatal health care and nutritional services for pregnant mothers and their children), we could reduce significantly the

incidence of the organic forms of mental retardation. These procedures would have a much smaller impact on the incidence of the nonorganic forms of mental retardation. Nonetheless, had these procedures been in use, the number of organic retarded persons in our society could have been reduced from approximately 2 million to 1 million.

Our knowledge concerning the larger number of retarded persons without known organic involvement is woefully inadequate. The etiology of this form of retardation remains the most perplexing problem in the entire field (Clarke & Clarke, 1977; Zigler, 1967). The closest we have to a consensus is that this form of mental retardation reflects some complex interaction between genetic and environmental factors. Thus, it is clear that the discovery of the exact etiology of this condition must await the resolution of perhaps the thorniest issue in the behavior sciences, namely, the nature–nurture issue in regard to the development and variation of intelligence. That we are at a very early stage in our understanding of cultural-familial mental retardation is also displayed by the fact that there are yet no completely accepted operational definitions of either of the two major behavioral criteria used in defining mental retardation, i.e., intelligence and social competence (see Zigler & Trickett, in press, for a discussion of these complex definitional issues). Given the primitive state of our knowledge concerning the etiology of cultural-familial retardation, it is erroneous to claim that we are anywhere near having the information that could significantly reduce the incidence of this type of retardation.

Progress in our understanding of cultural-familial retardation will require a different approach than that which has advanced our knowledge in regard to the organic type of retardation. One need know only some of the most striking facts about cultural-familial retardation to realize that a behavioral approach is necessary to understand this type of retardation. Why is cultural-familial retardation so related to family income and parental occupation? Why is the prevalence of this disorder so much higher during the school years than in the postschool years? Why is IQ such a poor predictor of life outcome for this population of retarded individuals? These phenomena clearly have much more to do with behavior emitted, socialization, and social interaction than they have to do with defective physiological functioning. The knowledge needed to help this group of retarded persons will thus depend on a multidisciplinary effort that includes psychologists, educators, sociologists, social workers, and anthropologists, as well as behavioral geneticists, neuroscientists, and medical investigators. The theoretical problem of cultural-familial retardation is so all-encompassing that it can only be successfully attacked by workers committed to the examination of behavior within a framework that recognizes the interactive nature of the biological, social, and ecological determinants of behavior. I wish to be very clear on this point. I am not referring to scientists who have a PhD after their name as opposed to an MD. The distinction I am drawing centers about the importance the investigators attribute to the changing behavior of the person over the life span and a deep concern with how such behavior is influenced. Breakthroughs in this field will come from workers who are as interested in normal development as they are in physical disease. In the field of medicine, particularly pediatrics and child psychiatry, a hardy band of workers already exists with the necessary behavioral outlook.

It is ironic that the UPI report of Mrs. Carter's speech emphasized her view that "We need more research" ("First Lady Aids Retarded," 1977). The irony lies in the fact that America's research workers in the area of mental retardation, and particularly behavioral scientists, are uneasy about the support that they can expect to receive for their efforts. We are currently experiencing a crisis in mental retardation research. The events of the near future will determine whether our nation continues its record of research accomplishment in the mental retardation field or whether, as appears more likely to this observer, the research effort

will be stopped in its tracks and the research edifice that has taken 20 years to build will be severely weakened.

A Brief History of Mental Retardation Research

This ominous warning can only be understood within the framework of the history of mental retardation research over the past 2 decades. Only 20 years ago, the mental retardation research area was a rather desolate field, poor in the quality of work being done, limited in the extent of the phenomena being investigated, and almost totally sterile in regard to theoretical formulations that could guide both researchers and practitioners interested in maximizing the potential of retarded individuals. Although now little more than a historic relic, about all we had in the way of theory was that retarded persons were inherently rigid individuals, a point of view that gave rise to training practices emphasizing teaching retarded persons perseverative tasks since they should love such tasks so very much.

The past 20 years, however, have brought a marked change in this state of affairs. Recent research in the mental retardation area is work of high quality that has made important contributions in improving the daily lives of retarded individuals. For example, intervention programs designed by Heber (Garber & Heber, 1977) for children vulnerable to mental retardation and by Hayden and Haring (1977) for children with Down's syndrome bear great promise for preventing or greatly diminishing cognitive retardation. The work of Butterfield and Belmont on short-term memory has influenced the development of teaching strategies that may help to overcome the memory deficits of retarded individuals (e.g., Butterfield, Wambold, & Belmont, 1973). Zeaman's (1973) work on attention deficits in retarded persons has given rise to classroom practices that aid teachers in maximizing the performance of retarded students. In addition, many teaching strategies developed for use with retarded students are now recognized as being beneficial for nonretarded students (Hobbs, Bartel, Dokecki, Gallagher, & Reynolds, Note 3). Research has also been directed at improving the care of mentally retarded persons. A number of workers are developing behavior modification techniques for use by parents of retarded persons (e.g., Heifitz, 1977). In many instances, these techniques have been not only a godsend for the parents but have permitted retarded individuals to remain in their homes rather than being institutionalized at great expense to taxpayers.

How can we explain this great improvement in mental retardation research? It is a success story involving certain institutional forces, certain individuals, and, finally, a Congress that had the wisdom to realize that our ability to help any group of individuals can never outdistance the verified knowledge we have about them. The concern and interest in mental retardation of President John Kennedy should certainly be noted, as well as the commitment of utilizing research to improve the lives of retarded persons made by NARC and the Joseph P. Kennedy Foundation. These various forces came together, and the Congress took the pivotal step of legislating the existence of NICHD. Congress also specifically requested that NICHD establish a network of mental retardation research centers in the United States. This network of 12 centers represents an intellectual resource that has no equal anywhere else in the world. Funds appropriated to NICHD each year to support the research centers and independent investigators have largely underwritten the success story that I have briefly outlined above.

Since the fate of mental retardation research in the United States is so intimately related to the policies and effectiveness of NICHD, it is of interest to note the division of opinion that existed among mental retardation workers in regard to the nature of the institute to be created. Two possibilities were originally discussed: (a) an institute solely directed towards research on mental retardation in the model of other disease-oriented institutes of health and (b) a much broader focused institute of child health and human development that would subsume mental retardation research activities. At that time I strongly favored the second al-

ternative. I did so because I felt that the best way to enhance our understanding of mentally retarded persons was through the general investigation of normal human growth and development. I remained sanguine about this decision for those many years in which no exception could be taken to the excellent manner in which NICHD built up our nation's capability in the mental retardation field. I am now no longer sanguine and admit openly that I did not anticipate the risk in the alternative I supported. This risk resides in the fact that mental retardation concerns at NICHD can be submerged by other research priorities. Thus, the success of the mental retardation research endeavor is held ever captive to the degree of personal support given to it by the director of NICHD. (It is not accidental that the most productive period of mental retardation research activities at NICHD took place when its director was Gerald LaVeck, an important scholar and investigator in the area of mental retardation.)

The issue of what kind of agency should represent the nation's commitment to solving the problems of mental retardation has recently been revived by the recommendation of the President's Committee on Mental Retardation (Note 2) that a National Institute on Mental Retardation be established. I do not believe that a separate institute is necessary; however, I would prefer a compromise position that would elevate the mental retardation research effort at NICHD from its current branch level to the status of a center. Such a change would be more than cosmetic. A Center for Mental Retardation would have more autonomy than does the present Mental Retardation Branch and, thus, could be more effective in advancing mental retardation research. In addition, the behavior sciences currently have no representation at high administrative levels nor any significant input in formulating policy. I propose, therefore, that an Associate Director for Behavior Sciences be appointed who could promote the behavior science effort at NICHD.

Another historical strand of importance is related to the role of the National Institute of Mental Health (NIMH) in mental retardation research. Prior to the formation of NICHD, NIMH was the major agency funding basic research in mental retardation. When NICHD came into being, most of NIMH's research holdings in mental retardation were shifted to NICHD. In addition, the director of NIMH made the decision that NIMH would no longer fund research in mental retardation. Thus, for all practical purposes, when research workers gained support of the funds of NICHD they lost those of NIMH. Abandoning the field of mental retardation by NIMH was not in the interest of researchers, retarded citizens, or the general public. Although the action of the director of NIMH was arbitrary and, given the legislative mandate of NIMH, of questionable legality, no one raised a public outcry. The situation was not even questioned until about 3 years ago when the directors of NICHD and NIMH convened a group of consultants[1] to examine how the two institutes could cooperate in the mental retardation field. This group of consultants prepared a report involving specific recommendations, many of which emphasized the importance of behavioral research efforts in the field of mental retardation (Ad Hoc Consultants on Mental Retardation, 1977/1978).

This brief overview should make clear why the policies of NICHD are so important to research workers in the mental retardation field. This institute is the only major source of funding for basic mental retardation research. It also plays the same role in regard to behavioral research in the area of normal growth and development. It is this dual role that probably explains why the current critics of NICHD represent, primarily, a mix of mental retardation researchers and researchers working on basic processes in the field of behavioral development.

Another factor that further highlights the importance of NICHD research support is the changing posture of NARC towards support of mental retardation and basic behavioral research. For many years NARC provided research support primarily to

[1] The members of this group were George Tarjan (Chairman), Sanford Dornbusch, Gerald Fenichel, Frances Graham, Julius Richmond, and Edward Zigler.

younger investigators in the biomedical and behavioral fields. A few years ago this model of research activity was abandoned in favor of an in-house research operation in which research would be conducted by employees of NARC. Whatever one thinks about the wisdom of the decision, NARC research income (primarily from donations by the NARC members) has shown a linear decrease from approximately $134,000 in 1965 to $74,000 in 1975. This decrease in funds in conjunction with the current view that NARC is no longer interested in supporting basic research means that basic researchers are coming ever closer to being totally dependent on research support from NICHD.

Just as NARC administrators seem to think that applied research has greater value than does basic research, we are currently in an era when many decision-makers assert that scarce tax dollars should be spent on research directed towards the solution of social problems rather than expended in pursuit of satisfying basic researchers' curiosity. Such a view is shortsighted and will lead to a diminution in gathering the knowledge that is so central to solving major social problems that confront the nation. There is no real distinction between basic and applied research. These efforts are totally synergistic and must be pursued simultaneously. As the Ad Hoc Consultants on Mental Retardation stated in their report (1977/1978): "The dichotomy between basic and applied research, in this as in other areas, is a false one. Fundamental advances in knowledge come from the general to the particular and vice versa" (p. 5).

The current crisis in the mental retardation research field and the accompanying state of malaise of mental retardation research workers has been precipitated by recent policies of NICHD. The institute increasingly appears to be committed to the expansion of efforts in the biomedical area in general and perinatal biology in particular. Efforts in the behavioral sciences, however, have not been strongly supported. These policies not only counteract an original intent to have NICHD as a focus of behavioral research but, more importantly, undermine the nation's capability of solving the many behavioral problems that still need to be solved if we wish to reduce significantly the incidence of mental retardation.

The make-up of NICHD's advisory council and the staffing pattern of the institute reflect the minimal attention given to mental retardation and the behavior sciences. Originally, over 40 percent of the council members were representatives from mental retardation and behavior science. Today, the council includes only one person from the behavior sciences and only one from the area of mental retardation. Several young behavioral scientists have left the institute after only brief periods of employment, and very few of those who remain occupy leadership and policy-making positions.

Funding patterns by NICHD also manifest, by program comparisons, a diminishing level of support of mental retardation and the behavior sciences. In 1976 the Pregnancy and Infancy Branch of the Center for Research for Mothers and Children, which supports biomedical research almost exclusively, received an increment of $3.3 million over 1974 funding levels. The Center for Research for Mothers and Children branches that support behavior science research, the Growth and Development Branch (recently divided into the Developmental Biology and Nutrition and Human Learning and Behavior Branches) and the Mental Retardation and Developmental Disabilities Branch, received increments of only $1.0 and $1.8 million, respectively. According to early reports on funding in 1977, only about 11 percent of funds requested by research applications in the behavior sciences were awarded by the Center for Research for Mothers and Children, whereas 30 percent of funds requested for biomedical science were awarded. Funding of the 12 Mental Retardation Research Centers, in terms of real purchasing power, is currently at about 50 percent of that of 7 years ago. The minimal support of behavior sciences is seen all across the National Institutes of Health (NIH). Currently, NIH has a budget of ap-

proximately $3 billion; only 1.6 percent of this amount serves to support behavior science research.

The problem of funding behavior science applications in the area of mental retardation does not rest solely with the policies of NICHD. Partial blame should be given to the scientific review given these applications. Most behavior science project applications assigned to the mental retardation program of NICHD are reviewed by the study section on Developmental Behavioral Sciences. This study section approves a much lower percentage of applications than do other study sections. Over the past year, their approval rate for Mental Retardation and Developmental Disabilities and Human Learning and Behavior applications was 27 percent; six other study sections approved a mean of 78 percent of such applications. Moreover, the Developmental Behavioral Sciences votes an atypical pattern of merit scores that further reduces the number of behavior science applications that are funded. Since awards are made on the basis of normalized priority scores, those applications approved by the Developmental Behavioral Sciences have less chance for award because their raw priority scores are made even poorer by normalization.

In response to the current policies of NICHD, the scientific community has engaged in a number of actions, none of which has proved to be effective in stemming the tide of the worsening situation at NICHD. Several past presidents of the Division of Developmental Psychology (Division 7) and the former president of the Division of Mental Retardation (Division 33) of the American Psychological Association have voiced their concern. The Social Policy Committee of the interdisciplinary Society for Research in Child Development has expressed very serious reservations about the current directions of NICHD. The situation in the mental retardation field has become so serious that an interdisciplinary group of senior research workers in the field met under the auspices of the American Association on Mental Deficiency to discuss how best to deal with NICHD's inadequate funding of research in mental retardation.

Research Needs

The greatest danger in NICHD's current policies is that they might drive a wedge between biomedical and behavior science. The rapprochement of the biomedical and behavior sciences in recent years has yielded important new knowledge in the health care field. A similar interdisciplinary effort in the field of mental retardation is not only desirable but essential. The biomedical sciences have greatly advanced our knowledge concerning the etiology of the organic types of mental retardation. The biomedical sciences alone, however, cannot advance our knowledge of the remaining 75 percent of cases, i.e., the nonorganic forms of mental retardation.

The need for behavioral research in mental retardation is seen in bold relief in the problem of the burgeoning number of teenage pregnancies. Many of the factors associated with mental retardation and physical ill health are found in teenage pregnancies and child-rearing. These factors include suboptimal reproductive age, inadequate prenatal and neonatal health care, maternal and infant malnutrition, and premature and low birth-weight babies. If we are interested in preventing mental retardation, it is not enough to learn what constitutes good prenatal and neonatal health care. We must also learn much more about why adolescent girls become pregnant in spite of the great availability of contraceptives, and why they are increasingly unwilling to give up their babies for adoption. If having and keeping a baby is a deliberate action to gain status or escape an intolerable social predicament, then behavioral studies should be conducted to find alternative means of satisfying these needs. Some research in this area is currently funded by NICHD, but the level of effort needs to be increased greatly.

In addition to biological factors listed above, many parental and home characteristics have been associated with the incidence of mental retardation. Impoverished homes, little sensory stimulation, absent fathers, and mothers who are emotionally or physically unavailable are the sort of deprived conditions in which the

majority of retarded persons have been raised. How these conditions retard cognitive development and what measures can be taken to overcome this effect are questions whose answers will most likely come from studies concerning the development of different motivational and value systems, different methods of transmitting culture from one generation to another, and the impact of person–setting relationships on individuals' development. We also need to learn what kind of social, emotional, educational, and environmental child-rearing conditions lead to optimal development in the individual. The incidence of mental retardation can be reduced by one-half only when we understand the contribution made by all the factors—biological, social, and environmental—that influence behavior.

Behavioral research is also needed to develop and evaluate services and programs that will improve the lives of retarded citizens and their families. The federal government is currently spending more than $1.5 billion on services and income maintenance for retarded citizens. The states are also spending many millions. The research effort in mental retardation, however, is less than 1.5 percent of the total public expenditures. Public policy is now committed to such concepts as deinstitutionalization and normalization. I join many workers in the field who view these concepts as little more than slogans that are badly in need of an empirical data base. We do not yet know what is the best type of classroom environment for retarded children nor what is the optimal institutional setting for those children who cannot remain with their families. Yet the nation is already spending vast amounts on putting into place practices that may ultimately be shown to have deleterious consequences. It makes little sense to spend hundreds of millions of dollars on questionable social practices and not provide adequate support to researchers committed to examining the effects of such practices. The only antidote we have to moving from fad to fad is careful behavioral research to provide scientific underpinnings for programs designed to benefit mentally retarded persons.

More research is also needed on ways to enhance the behavioral functioning of retarded individuals. Many specific areas of inquiry that can lead to improvements have been listed by Haywood (1976). In the subject of human learning, for instance, we need to know what educational, social, and motivational factors influence learning and how these factors interact. We already know that several motivational dispositions in cultural-familially retarded persons attenuate their cognitive performance (Zigler, 1966; Zigler & Balla, 1976). In what ways may these detrimental dispositions be overcome? We also need to determine what factors can enhance cognitive performance and, thus, increase the number of retarded persons that may be educated and trained to do useful work. Research in this field quickly leads to economies that, in essence, make the research endeavor a fiscally self-supporting one. As Mrs. Carter noted in her speech (Note 1), for every dollar that is spent on educating a retarded adult male, $14 is returned during the individual's lifetime.

Every research field needs more money. Then why single out the mental retardation area for special munificence? The two overriding criteria that I employ in determining my views concerning the allocation of federal money are: (a) the extent of the human need and (b) the discernible benefits that can be demonstrated to accrue from such public expenditures. In regard to need, if one uses the most accepted prevalence figures for mental retardation, approximately six million children and adults in the United States are mentally retarded. As a major health problem, this figure is exceeded only by mental illness, cardiac disease, arthritis, and cancer. In regard to the cost–benefit issue, I refer you to Conley's fine book, *The Economics of Mental Retardation* (1973), in which he makes clear that investment in the mental retardation area provides all of society with real dollars-and-cents benefits as well as important human benefits.

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CONTRIBUTIONS TO HEALTH CARE

Senator HATFIELD. One last question, Dr. Kretchmer: What would you in your general estimation consider to be the most productive areas in relation to the contributions to health care of the world, especially in the general area of biomedical research? What areas would you consider to have made the best contribution to the raising of the standards in the last several years?

Dr. KRETCHMER. Well, I would have to preface my remarks by saying my background is in the basic sciences.

I would say that the greatest contributions to health care in the world have been the advances that are most dynamic, the unbelievable advances over the past 20 years that we have seen in basic science, and our understanding of how molecules and cells interact with one another.

The contributions from those areas can be tracked to almost everything that we have today.

As a matter of fact, this was the subject of a book written recently, "The Retrospectroscope," written by Julius Comroe.

There is no question in my mind that the advances of basic science have contributed most to where we are today. There is no question about that.

I must say, just to take advantage of the floor at the moment, I was going to say fetal medicine, but the way you worded your question, I would have to say the basic sciences.

Senator HATFIELD. What kind of a question should I have asked—

Dr. KRETCHMER. No. I am delighted to answer the question the way I did, because I'm a fanatic about this, and we could take example after example of what we now know to be accomplished.

Take a coronary bypass. If we didn't know anything about tissue culture, and the early work which goes back actually 70 years, we wouldn't be doing bypasses in the heart.

Dr. FREDRICKSON. I think today's research is tomorrow's medical care, that the effect research has on a given area of disease or disability, it often related to the technical opportunities that exist.

Certainly if we went back 100 years ago to bacterial disease, and what has ensued from that, in terms of infectious disease, that almost certainly is more dramatic than any other area.

Now we are beginning to change, having conquered much of that, not all of it, and moving into the areas of chronic disease.

But it is probably true today that there is more opportunity than there ever has been, in the sense that science continues to grow, and on that analogy the opportunities seem to flourish.

QUESTIONS SUBMITTED FOR RESPONSES

[The following questions were not asked at the hearing, but were submitted to the Department for response subsequent to the hearing:]

NUTRITION

Question: Last year in its report, the Committee noted that you were planning to increase your research in the area of nutrition and maternal health and fetal development. What are your plans for this in 1980 and what exactly are you looking for or trying to do in this program?

Answer: The growing fetus must rely entirely upon its mother for its nutrient supply. The growth of the fetus is therefore affected by the nutritional state of the mother before pregnancy and by the kind and amount of food she eats during pregnancy. Because of the importance of maternal-fetal nutrition, the National Institute of Child Health and Human Development since its inception has supported research on the effects of maternal nutritional state on fetal and infant development.

Current research aims of this program include:

- Establishing the nutritional requirements of the mother during pregnancy which reflect the nutritional demands of the growing fetus.
- Ascertaining patterns of absorption and disposition of nutrients by the mother during pregnancy.
- Measuring the efficiency of transport of nutrients from mother to fetus.
- Ascertaining specific causes of intrauterine growth retardation of the fetus.
- Improving the ability of medical personnel to identify early in pregnancy those mothers who are at risk for producing a baby who fails to grow normally in the uterus.
- Developing methods of treatment for intrauterine growth retardation by providing nutritional therapy to the materno-fetal unit and by providing the dwarfed newborn with specially tailored growth-promoting nutritional therapy after birth.
- Documenting the types, extent, and effects of food cravings and aversions among pregnant women.

CONGENITAL DEFECTS

Question: Has NICHD's effort toward prevention of congenital defects gained momentum, and what specific research programs were started in 1979?

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Answer: Prevention of congenital defects has been established as the goal of many research programs supported by NICHD. The task is a difficult one since about 60% of all birth defects are the result of unknown causes. New research efforts are focusing on studies of the underlying gene-controlled cellular and molecular processes that contribute to congenital defects; exploring through clinical and biochemical studies the mechanisms responsible for neonatal dwarfism (short-limbed syndromes), and support of the development of animal models that mimic various common congenital defects in humans.

In FY 1979, NICHD is supporting an in-depth review of the multiple aspects of antenatal diagnosis of congenital defects and inborn errors of metabolism to determine the state of the art, to identify gap areas in knowledge, and to stimulate intensive studies in the many facets of the problem.

LEARNING FAILURE

Question: Children from the lowest socioeconomic groups (unskilled and unemployed) have twice the rate of school learning failure than higher occupational groups. Research reports suggest that environmental conditions are more determinative of this developmental outcome than biomedical factors implicated in the damaging events of pregnancy, birth and the perinatal period. Is this true?

Answer: It is true that environmental conditions, such as socioeconomic status, parental values, and parent-child relationships are more likely to relate to a child's success or failure in school than biomedical factors such as birth defects.

Strong supporting evidence comes from a longitudinal study of children in Hawaii where the biomedical factor of perinatal stress was compared to a variety of environmental conditions (home educational stimulation, socioeconomic status, and maternal education) as predictors of later academic achievement. Ten times more children had school and learning problems attributed to the effects of a poor environment than to the effects of serious perinatal stress.

Question: How does NICHD propose to address this issue, and what will be its balance of effort devoted to environmental (behavioral and social), as opposed to biomedical, research?

Answer: The NICHD recognizes the importance of both biological and behavioral factors in this and other aspects of human development. The Institute draws upon many disciplines to study the learning process by supporting fundamental research in such areas as perception, attention, memory, motivation and cognitive development. Also important are familial and social factors which affect the child's behavior at home and in school. As an example, one of our grantees is studying the development in young children of such processes as self control, resistance to temptation, delay of gratification, ability to sustain goal directed work and self regulation in achieving goals--all precursors of cognitive development and related to later school success.

Furthermore, the NICHD currently supports both biomedical and behavioral research aimed at improving the diagnosis and treatment of children who suffer from specific learning disabilities, particularly the reading disorder, developmental dyslexia, which affects millions of Americans. Through such research we hope to better understand the biological and psychological bases of language and the related process, reading, in order to identify those factors which may interfere with the normal acquisition of the skills necessary for school achievement.

In FY 1978, overall Institute support amounted to approximately $16.6 million for research related to learning and cognitive development. Almost seventy-five percent of that figure represents behavioral research while twenty-five percent reflects research with a major biomedical component. In FY 1980 we would anticipate a similar proportion of effort in this area.

DIABETES

Question: Has there been any recent progress on maternal diabetes research?

Answer: It has recently been established that careful control of the level of blood sugar during the last trimester (three months) of diabetic pregnancies greatly improves the rates of mortality and morbidity of both the diabetic mother and her newborn.

Because of this encouraging success in the last trimester, the NICHD is now supporting a clinical trial of careful control of maternal blood sugar during the first trimester of pregnancy to discover if the high incidence of fetal malformations which occurs in diabetic pregnancies can be lowered by this treatment. On a theoretical basis, manipulations of levels of blood sugar carried out during pregnancy could affect the incidence of congenital defects only during the early weeks of pregnancy when fetal limbs and other organs are forming.

Ultrasound is now used in the treatment of diabetic pregnancies. The development of very large babies (in excess of 10 pounds at birth) and the appearance of cardiac and neural tube defects can now be visualized in diabetic pregnancies. The use of ultrasonography also allows exact plotting of the rate of fetal growth during the diabetic pregnancy and permits the prediction of macrosomia, i.e. a very high birthweight.

An animal model of macrosomia has been produced in newborn monkeys by giving their mothers large amounts of insulin during the last third of pregnancy. This demonstration bolsters the theory that insulin acts to promote growth of the fetus.

A new biochemical technique, the measurement of glycosylated hemoglobin (Hemoglobin A_{1c}), is now being used successfully to indicate the degree of control of levels of blood sugar over relatively long periods of time (weeks and months) in diabetic pregnancies. This new diagnostic tool should be of value in managing diabetic pregnancies.

GENETIC COUNSELING

Question: I understand that your Institute does a lot of genetic work as well as the General Medical Sciences Institute, Dr. Kretchmer. Could you give us some examples of how the combined efforts of Health Services Administration, your Institute, and other programs in the Public Health Service concerning genetic counseling are being brought to the attention of the public?

Answer: The NIH established a Genetics Coordinating Work Group in May, 1976, to provide advice and recommendations to the Director, NIH, regarding implementation of the provisions of the National Sickle Cell Anemia, Cooley's Anemia, Tay-Sachs and Genetic Diseases Act. This Act provides for a national program of basic and applied research, research training, testing, counseling, and information and education programs with respect to genetic disease. The group was expanded to encompass representatives of the other health agencies, was formally chartered as the Public Health Service Genetics Coordinating Committee, and has provided information exchange and understanding between HSA and NICHD.

A public meeting was held December 7-8, 1977 at NIH to which professional and lay persons interested in and knowledgeable about genetic services were invited to give testimony regarding particular areas covered by the Act. As a result, a panel on counseling has provided a set of recommendations for counseling on genetic diseases.

The Health Services Administration is responsible for the provision of services, under the Act, which include counseling as well as a program to develop information and educational materials relating to genetic counseling. A contract has been awarded by the Health Services Administration to plan and establish a center and clearinghouse for human genetics.

The National Institute of Child Health and Human Development has submitted to this contractor educational materials on genetic diseases and counseling which will be included in a 1979 catalog of selected educational and informational materials. The catalog will be distributed nationwide. In this way, a combined effort is being made to keep the public aware and provide them with information on a continuing basis.

CHILD ABUSE

Question: Is there a child abuse research program currently being funded by NICHD? Could you tell us about it, as you have not mentioned it in your program curriculum, yet it is a major social problem in the United States today?

Answer: Within the Department of Health, Education, and Welfare, research on child abuse and neglect is supported by the National Institute of Mental Health and the Administration for Children, Youth and Families.

The NICHD, however, conducts and supports research that seeks to improve the health and well-being of women, children and families. Within this broadly defined area, research is conducted that indirectly bears on the prevention of child abuse and neglect. Included are studies on parent-child relationships and family interaction patterns during early infancy and childhood because these early bonding behaviors are believed to play an important role in motivation, ego development, ability to accept responsibility and self-control in later life. The development of moral values, self concept, and personal esteem is studied to learn how experiences during adolescence affect behavior in adult life.

Demographic studies focus on how couples make decisions about child bearing, the changing role of women as effected by separation, divorce, and remarriage, and the effects of single-parent homes on the social development of children and on the attitudes of parents toward their children.

Studies on the consequences of unwanted births for the mother and child are supported with a focus on the effect of birth order and spacing of children on mother-infant relationships and on the emotional development of children. By increasing knowledge of the factors associated with normative behavior and child rearing practices, the Institute contributes to the prevention of child abuse and neglect.

In addition, Institute personnel participate on national committees concerned with child abuse and neglect such as the National Center on Child Abuse and Neglect review panel on Evaluation of Clinical Demonstrations of the Treatment of Child Abuse and Neglect, and the National Advisory Board on Child Abuse and Neglect.

INFANT MORTALITY

Question: Could the incidence of infant mortality and morbidity in the U.S. be brought to par with that of other developed nations through improved delivery of health services utilizing existing research knowledge?

Answer: The applicability of existing research knowledge to the total population of the U.S. can bring the incidence of infant mortality and morbidity to par with that found in other developed nations. However, it should be noted that the present incidence in the U.S. is a composite figure encompassing a heterogeneous population ranging from a group having a low incidence to another where it is similar to that found in underdeveloped countries. Thus, to be successful in lowering the overall incidence in the U.S., the plan for the delivery of updated health services (medical-epidemiological, educational, etc.) must be designed to give greater priority to high-risk groups.

INFANT MORTALITY AND NEW RESEARCH FACILITY

Question: The incidence of infant mortality is highest in the lower socioeconomic class. To what extent and how do the Major Research Programs and the proposed new intramural and clinical research facilities relate to the socioeconomic and other social problems implicated in the higher incidence of infant mortality and morbidity among the lower socioeconomic class?

Answer: The six Major Research Programs (MRPs) administered by the NICHD include one program emphasizing the prevention of prematurity through study of the initiation of human labor, four are concerned with the problem of diabetes mellitus in pregnancy, one is directed toward the study of the biological and psychological aspects of Sudden Infant Death Syndrome (SIDS). These problem areas all contribute to higher infant mortality and morbidity, frequently with much higher rates among the lower socioeconomic groups. These MRPs represent an important commitment on the part of the NICHD to implement a long-range goal to prevent complications in pregnancy, to reduce this country's infant mortality rate, and to ameliorate infant morbidity at all socioeconomic levels. Study populations in the MRPs involve several strata of socioeconomic groups.

In the NICHD Intramural Research Program behavioral science projects are studying the effects of antenatal care, mother-father interactions in labor and during delivery on later mother-father-infant interactions. The mother-father-infant interaction is being studied in a middle-class group and a lower socioeconomic group.

The proposed clinical research facility would largely concentrate on those problems of the perinatal period which are most common in the lower socioeconomic group--the high risk pregnancies. There would be obstetrical, pediatric and behavioral scientists collaborating to study these problems.

Question: Concentrations of research effort already exist in the U.S. for conduct of research proposed for the extramural clinical research facility. To what extent does the proposed facility duplicate existing research effort in the major research and training institutions in the U.S.?

Answer: There should be no duplication of research in the proposed clinical research facility. In addition to serving as a principal component of the NICHD intramural program, this facility would serve as a coordinating unit for interaction of scientists in the extramural centers. It would serve as a conduit for the exchange of research information between the several units. This would further reduce the likelihood of duplication and facilitate collaborative coordination of research projects. It would be much easier to initiate clinical trials if such a network were in existence. It would then follow that important questions could be posed, the design of approach fashioned and the study initiated with a significant reduction in time. Sufficient patients and controls could then be obtained by widely scattered centers to obtain definitive

answers. The facility would also serve another purpose. Currently there is no single facility doing the type of clinical research with an interdisciplinary approach to both obstetrics and pediatrics that is envisioned in this new clinical facility.

MONGOLISM

Question: What research efforts directly concerned with Down's Syndrome (Mongolism) are on-going in the NICHD Intramural Research Program?

Answer: Although the NICHD has an active extramural program directly concerned with Down's Syndrome, there are currently no on-going studies in the Intramural Research Program.

CONTRACEPTION

Question: Over the past few years, the Committee has received testimony from you and others describing new contraceptives for both men and women. At what stage are we in this technology and how far are we away from having safe and effective contraceptive alternatives for consumers?

Answer: In answering this question it is important to realize that contraceptive technology represents many different approaches. The three basic approaches are represented by new drugs and new methods of their administration, contraceptive devices, and finally, contraceptive methods which depend on abstinence. Several potentially useful drugs have been identified for contraceptive purposes. Plans for their in-depth clinical investigation have been formulated. Taking into account the current FDA requirements, it is very unlikely that these drugs will reach the consumer in less than 15 years. Similarly, the new methods of drug administration that are likely to reduce the amount of needed drug are also some five years away from marketing. With respect to devices, the situation is somewhat more optimistic in that programs designed to improve vaginal barrier methods of contraception are underway and are likely to have a more rapid transition period from the testing period to consumers. Finally, we have completed studies that clearly indicate that couples can identify the fertile and infertile phases of the woman's cycle. They can utilize this information for family planning purposes. Among couples using the so-called symptothermic method, the failure rate was about 10 percent and among couples using the so-called ovulation method, it was about 20 percent. Among the symptothermal method users as well as among the ovulation method users the high failure rates were due primarily to the fact that couples did not abstain from intercourse when they knew that the woman was in the fertile phase. This information is of immediate impact on consumers using these methods.

Question: In your opinion, just how safe is the "Pill"?

Answer: The clearest criteria of safety is the risk of death. For women less than 30 years of age, the risk of death which is associated with the use of oral contraceptives to regulate fertility appears to be similar to the risk of death which is associated with the other reversible methods of birth control that are currently available (intrauterine device, diaphragm or condom, etc.). When used alone, each of these reversible methods of birth control appears to be associated with between 9-18 deaths per 1,000,000 users per year, either directly from the method or from resulting pregnancies in cases where the method failed.

For women 30 years of age and older who smoke cigarettes, current data indicate that the risk of death which is associated with the use of oral contraceptives is substantially larger than the risk which is associated with other reversible methods of birth control. For example, among women 40-44 years of age who smoke cigarettes, the use of oral contraceptives appears to be associated with about 589 deaths per 1,000,000 users per year. The comparable figure for nonsmokers who use oral contraceptives is 71 per 1,000,000 users per year. For women 40-44 who use the intrauterine device, the comparable figure is 19 per 1,000,000 users per year.

The major question about the safety of oral contraceptives which has not yet been adequately explored involves the relationship between oral contraceptive use and the occurrence of various benign and malignant tumors (especially breast cancer). Because the induction of most tumors proceeds very slowly, rigorous study of this issue has become feasible only in the last few years. Major research projects in this area are underway.

CHILD HEALTH BUILDING

Question: Last year, Congress provided $37 million to construct a new Child Health Research building on the NIH campus. This has turned out to be quite a controversial issue. Many people oppose it and many are for it. Now, the President has proposed that we rescind all of the funds for this construction project. The White House feels as though, among other reasons, that the NIH Intramural Research programs are strong enough and that, in fact, the universities should be doing any expanded programs in this area. I also understand that some people would rather use that $37 million for research programs and not for construction. How do you feel about this?

Answer: In requesting the rescission of funds for the NICHD building, the President chose to reduce building funds rather than program funds, and I agree with that choice. However, it is important to remember that the original $37 million appropriated was not taken from, or even intended to be used for an extramural program expansion. As a matter of fact, the building itself does not imply any expansion of the NICHD Intramural Research Program, but rather a consolidation of this program from nine widely scattered buildings where scientists work under crowded conditions, into one modern facility with adequate space. Finally, it should be noted that construction of this NICHD facility represents an essentially one-time outlay of funds, whereas a program expansion adds to a program base with a commitment for continued funding in future years.

ACCESS TO NATIONAL CANCER PROGRAM

Senator HATFIELD. Senator Burdick, I'm sorry, I didn't see you come in. Good morning.

Do you have a question that you would like to propound?

Senator BURDICK. If it is in order, I would like to ask a question of Dr. Upton.

I understand that the report that accompanied the 1974 amendments to the National Cancer Act directed that all Americans have access to the national cancer program, regardless of where they live.

The citizens of North Dakota have often been shortchanged in national efforts like this, because we have no major medical research facility in our state.

Can you tell me what you have done to carry out the 1974 directive in the north-central States of North and South Dakota, Montana, Iowa, Nebraska, and Minnesota? I realize there is a good deal of cancer research going on at the Mayo Clinic, at the University of Minnesota, but what are you doing to see that the people of this region get the benefit of that research?

Dr. UPTON. Mr. Chairman, I would have to provide a detailed answer to your question for the record.

I can only say that the clinical cooperative program supported by our Division of Cancer Treatment does in fact extend into the northwest region. Hundreds of institutions are cooperating and promoting the best use of advanced forms of treatment of cancer, and their efforts are being extended by our cancer control program, which takes those activities out into the community hospitals.

We have close to 50 percent of all community hospitals in this country with 50 or more beds involved in programs supported by that division.

These programs involve the provision of care to cancer patients, information on means for protection and diagnosis of cancer, preventive activities, and information for the public as well as health care professionals.

It is true that the amount of money spent in North Dakota, particularly, is not as large that spent in other States. But the effort is being made to extend access and opportunities through our program into that region of the country.

[The information follows:]

CANCER RESEARCH BENEFITS

The community and outreach programs of the Mayo Clinic are designed to see that the people of this region receive the benefits mentioned. The programs capitalize on a long established and strong relationship with the patients and physicians in the region. In cooperation with the NCI Division of Cancer Control and Rehabilitation, Mayo has developed new and imaginative programs in cancer communications and rehabilitation involving patient education, regional outreach, and rehabilitation research. These programs include: Comprehensive Cancer Center Communications; Review of Breast Cancer Detection Demonstration Programs;and Demonstration of Cancer Rehabilitation Facilities and/or Departments. In addition, the Cancer Control Program has supported, for example, the North Dakota State Department of Health in the State Cervical Cancer Screening Program. A list of Cancer Control Program support to the north-central states region follows:

North Dakota

1. Contractor: North Dakota Department of Health
   Contract #: CN-55209
   Title: State Cervical Cancer Screening Program
   Total Obligated Through FY 1978: $49,268

2. Contractor: North Dakota State Department of Health
   Contract #: CN-65370
   Title: State Cervical Cancer Screening Program
   Total Obligated Through FY 1978: $175,382

South Dakota

3. Contractor: South Dakota State Department of Health
   Contract #: CN-55164
   Title: State Cervical Cancer Screening Program
   Total Obligated Through FY 1978: $93,272

Iowa

4. Contractor: Iowa Lutheran Hospital
   Contract #: CN-45067
   Title: Breast Cancer Detection Demonstration Project
   Total Obligated Through FY 1978: $957,943

5. Contractor: University of Iowa
   Contract #: CN-45125
   Title: Cancer Training Program for Physical and/or Occupational Therapists
   Total Obligated Through FY 1978: $178,814

6. Contractor: University of Iowa
   Contract #: CN-55061
   Title: Demonstration of Benefits of Early Identification of Psychosocial Problems and Early Intervention Toward Rehabilitation of Patients
   Total Obligated Through FY 1978: $384,457

7. Grantee: University of Iowa Hospital
   Grant #: CA-18139
   Title: Community Based Therapy for Children with Cancer
   Total Obligated Through FY 1978: $1,231,507

Nebraska

8. Contractor: State of Nebraska Department of Health
   Contract #: CN-45081
   Title: State Cervical Cancer Screening Program
   Total Obligated Through FY 1978: $455,921

Minnesota

9. Contractor: Minnesota Department of Health
   Contract #: CN-45105
   Title: State Cervical Cancer Screening Program
   Total Obligated Through FY 1978: $28,394

10. Contractor: Mayo Foundation
    Contract #: CN-45120
    Title: Demonstration of Cancer Rehabilitation Facilities and/or Departments
    Total Obligated Through FY 1978: $590,705

11. Contractor: Mayo Foundation
    Contract #: CN-45124
    Title: Study of the Incidence and Natural History of Genital Tract Anomalies and Cancer in Offspring Exposed in Utero to Synthetic Estrogens
    Total Obligated Through FY 1978: $1,530,613

12. Contractor: Mayo Foundation
    Contract #: CN-55242
    Title: Comprehensive Cancer Center Communications
    Total Obligated Through FY 1978: $534,131

13. Contractor: Minnesota Department of Health
    Contract #: CN-55264
    Title: State Cervical Cancer Screening Program
    Total Obligated Through FY 1978: $990,242

14. Contractor: Mayo Foundation
    Contract #: CN-75379
    Title: Review of Breast Cancer Detection Demonstration Programs
    Total Obligated Through FY 1978: $220,340

15. Grantee: University of Minnesota
Grant #: CA-19490
Title: Home Care for Child with Cancer
Total Obligated Through FY 1978: $362,210

Montana--None

For some time the National Cancer Institute has encouraged the involvement and participation of various geographic areas in the conduct of clinical trials. Following is a list of those institutions in the north-central states which are affiliated with the clinical cooperative groups supported by the NCI, Division of Cancer Treatment. Through membership in these groups, the institutions and over 170 individual investigators in these institutions are made aware not only of the activities at the Mayo Clinic, but of all the relevant activities of the National Cancer Program.

Clinical Cooperative Group Members North Central States

VA Hospital
Des Moines, Iowa

Iowa Methodist Hospital
Des Moines, Iowa

University of Iowa
Iowa City, Iowa

VA Hospital
Iowa City, Iowa

Marian Health Center
Sioux City, Iowa

Iowa Oncology Research Assoc.
West Des Moines, Iowa

*Duluth Clinic
Duluth, Minnesota

University of Minneapolis
Minneapolis, Minnesota

United Hospitals (Miller Div.)
St. Paul, Minnesota

Mayo Clinic
Rochester, Minnesota

*St. Cloud Internists, Ltd.
St. Cloud Minnesota

Univ. of Minnesota Hosp.-Minn.
St. Cloud, Minnesota

St. Paul Children's Hosp.
St. Paul, Minnesota

Hennepin County Medical Center
Minneapolis, Minnesota

Minneapolis Children's Hospital
Minneapolis, Minnesota

Mount Sinai Hospital
Minneapolis, Minnesota

St. Louis Park Medical Center
Minneapolis, Minnesota

St. Mary's Hospital
Minneapolis, Minnesota

Univ. of Minnesota
Minneapolis, Minnesota

VA Hospital
Minneapolis, Minnesota

Univ. of Nebraska Medical Center
Omaha, Nebraska

*Quain & Ramstedt Clinic
Bismark, North Dakota

*Fargo Clinic
Fargo, North Dakota

*Grand Forks Clinic, Ltd.
Grand Forks, North Dakota

*Donahue Clinic (Central Plains)
Sioux Falls, South Dakota

*Billings Clinic
Billings, Montana

*Internal Medicine Specialties
Lincoln, Nebraska

*Charter members of the North Central Cancer Treatment Group (NCCTG)

The National Cancer Institute through the Division of Cancer Treatment continues to encourage the establishment and development of regional cooperative efforts for the conduct of clinical trials. In June 1977, a nucleus of institutions on the above list (marked by asterisk*) formed the North Central Cancer Treatment Group (NCCTG). Their request for NCI support of their research is currently under review. The NCCTG, the first cancer treatment research cooperative group made up solely of community clinics, was assisted in its development by a Cancer Center Support (CORE) Grant from the Cancer Centers Program to the Mayo Clinic. The NCCTG is based on the premises that high quality cancer care can be delivered by the community clinic and that cooperative cancer treatment research conducted at the community clinic level provides the ultimate proving ground for applicability of new cancer treatment procedures to the general population. Headquarters of the NCCTG is at the Mayo Clinic.

Community Cancer Treatment

Senator Burdick. You have already answered my next question somewhat.

What do you think of going into a rural region like this?

Dr. Upton. I think those regions are critical, Senator Burdick. Without reaching out and involving health care professionals at a community level, we cannot expect to accomplish our mission.

Eighty percent of the cancer patients in this country receive their initial diagnosis and treatment at the community level, making it critical that our network of cooperating institutions reach out and embrace community hospitals and health care professionals working in the community.

That is our goal. We are working with health departments, to make that happen. I would be happy to provide a more detailed response for the record.

[The information follows:]

There are four major thrusts being tested by the cancer control program. First is the community oncology program for improving care through cancer treatment centers. Its focus is on improving diagnosis, treatment, and rehabilitation of cancer patients managed in community hospitals either connected with more cancer experienced hospitals for referral and consultation or in a community where remoteness from such hospitals occurs. Second, the cancer control activities with the clinical cooperative study groups also outreach to patients, physicians, and community hospitals by taking on these hospitals and physicians as affiliate members. Third, the cancer center outreach program has a major thrust in providing education and consultation to physicians near to and in areas remote from the center. The fourth program involving patients and physicians using community hospitals is the community-based program. This approach is expensive due to the comprehensiveness of the program and is least adaptable to small outlying communities unless approached from a statewide basis. Acceptance in all communities can be limited if the program is managed on a regional basis.

All of the approaches to improving care of cancer patients treated in community hospitals are in the initial test phase. All are expected to be viable and beneficial

approaches to improving care throughout the United States. The community oncology program (COP) is in the process of being greatly expanded for its second phase of testing. Three basic settings are being investigated as appropriate places where the COP approach can benefit. These are:

1. Small remote communities where there are only community hospitals with no possibility for an effective affiliation with teaching hospitals and cancer centers.
2. Larger communities where a group of community hospitals could possibly have affiliation with more cancer experienced hospitals, yet, by choice, do not.
3. Communities with a group of community hospitals that are affiliated with a teaching hospital but with limitations (geographically and referral patterns) in the help they can obtain.

These settings are basically where we have seen a proven COP approach being effective. It has been estimated that there are some 4,000 community hospitals with 50 beds or less. Other estimates are that 80 to 90 percent of patients are treated in the community outside of major medical centers such as teaching hospitals and cancer centers. With these estimates, plus early indications that the COP approach is viable and effective, the cancer control program staff sees the COP model as a means to: (1) reach those practitioners and hospitals with modern, multidisciplinary patient management protocols; (2) set up means for the practicing community to obtain consultation from more experienced cancer specialists; and (3) establish improved referral patterns. Therefore the COP will most probably be the model to be used (along with an expanded outreach program from cancer centers) for improving care in remote, rural communities not readily served by larger, more cancer-experienced institutions.

CLINICAL RESEARCH GROUP

Senator BURDICK. I understand your Institute has supported efforts by the Mayo Clinic to organize a clinical research group in this region.

This seems to me to be a viable way to fund research, while at the same time make the benefits of our research available to more people. I hope you will continue to support this kind of endeavor.

Dr. UPTON. We are indeed looking to that group for service to that part of the country, and it is our intention to support them to the best of our ability.

Senator BURDICK. Thank you, Mr. Chairman.

Senator HATFIELD. Thank you. We are quite happy to have you here. Senator Burdick.

All right, let's shift gears.

National Institute of Environmental Health Sciences

STATEMENT OF DAVID P. RALL, DIRECTOR

ACCOMPANIED BY:

DONALD S. FREDRICKSON, DIRECTOR, NIH
PAUL G. WAUGAMAN, EXECUTIVE OFFICER, NIEHS
NORMAN D. MANSFIELD, DIRECTOR, DIVISION OF FINANCIAL MANGEMENT, NIH
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1979 APPROPRIATION AND 1980 BUDGET REQUEST

Senator Hatfield. Dr. Rall, you are our next witness, and you will be testifying on the budget request for environmental health sciences.

Your budget is requesting $79,012,000, an increase of approximately $900,000 over last year's level.

PREPARED STATEMENT

We do have your full statement here, Dr. Rall, which will be placed in the record. And if you will briefly sumamrize that statement for us, we will get on to the questions that the staff has prepared.

[The statement follows:]

STATEMENT OF DAVID P. RALL

Mr. Chairman and Members of the Committee

It is a pleasure to appear before you today to talk about the programs of the National Institute of Environmental Health Sciences, and discuss how these programs protect the health of the American people through research into the causes of environmentally induced disease and disorders. I shall also discuss the new and exciting National Toxicology Program recently announced by Secretary Califano.

I have previously talked to the Committee about the problem of dioxins. 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD) is probably the most toxic man-made substance known. Dioxins per se are of no commercial interest or value. However, they are created as contaminants during the manufacture of many commercially important chemicals. Polychlorinated Dibenzodioxins are found in some fungicides, herbicides, disinfectants and wood preservatives.

Studies in laboratory animals have shown that dioxins can cause birth defects, alterations in the immune system--allowing a higher incidence of infectious disease, severe skin eruptions called chloracne, changes in liver function, and an inability to gain weight. Some of these symptoms were observed in humans exposed in Seveso, Italy after a chemical factory accident spewed TCDD over a nearby residential area. The herbicide Agent Orange used extensively in Viet Nam as a defoliant was contaminated with TCDD, and similar health problems have been claimed by those who came in contact with it.

In a study just completed, our scientists have found that the contaminants in a wood preservative, pentachlorophenol, which includes other dioxins, dibenzofurans and hexachlorobenzene produce a number of toxic effects in cattle. This information is important for farmers who use pentachlorophenol treated wood to construct cattle barns and fences. Cattle exposed to pentachlorophenol showed a number of the physiological changes that I have already mentioned as associated with dioxin. Such cattle require considerably more feed to gain a weight equivalent to those not exposed to the dioxin. This could mean the difference between profit and loss for owners of the cattle. Not only does this present an economic problem but the health of humans who ultimately consume the meat and milk from the cattle might also be compromised.

The Polychlorinated Biphenyls (PCBs), are a group of halogenated aromatic hydrocarbons used for years as a fire resistant heat transferring agents or insulating fluid in transformers, in ballasts of fluorescent lights and many other applications. They have been identified with certain human health effects including general malaise, changes in the immune system and loss of muscle strength. PCBs are no longer made, however large quantities are still in use, and will continue to threaten human health.

NIEHS scientists are asking if PCBs in milk pose any hazard to offspring who nurse. This prospective epidemiological study is being conducted in cooperation with two North Carolina hospitals and one women's clinic.

The study is designed to determine the effect, if any, the presence of PCBs and other environmental chemicals in mother's milk might have on the health of her child. The children are being evaluated over the first six months of life with particular attention paid to growth and development. They will be followed until school age in order to assess possible learning and behavior problems.

NIEHS grant supported research using nonhuman primates has shown that PCBs also cause a host of reproductive problems. The menstrual cycle of rhesus monkeys was altered and the conception rate showed a considerable decline. Spontaneous abortion and fetal wastage were both common in monkeys fed an experimental diet containing PCB.

Detecting minute quantities of environmental chemicals in mother's milk and in all biological systems is a difficult problem. The standard assay method to date has used mass spectrometry, a slow expensive method requiring extensive training. This situation has been largely responsible for the slow output of analytic data. Responding to the need for new test systems, Institute scientists have been developing and perfecting a specific analytical process using the radioimmunoassay technique. When this test is perfected, scientists will be able to identify minute quantities of toxic substances in some instances down to the parts per trillion range. Radioimmunoassay is less expensive and more rapid than the now standard use of high resolution mass spectrometry. Most hospital laboratories already possess the equipment and trained personnel necessary to do radioimmunoassays.

Since current studies suggest that about 80% of synthetic organic chemicals showing mutagenic properties may eventually display carcinogenic potential, the Institute is continuing to develop a testing program that will screen chemicals for mutagenic activity. The tests start with special strains of highly sensitive

microorganisms such as salmonella and neurospora then use fruit flies (Drosophila) and/or mammalian tissue cultures. The program has been designed with quality validating procedures, assuring that different laboratories arrive at the same results, with the same chemical. The initial list of over 200 chemicals to be tested has been drawn up by our Chemical Selection Committee. Initial test protocols have been set up so that first phase testing can be completed on any chemical within 2-4 weeks.

One of the most ubiquitous environmental contaminants is lead. Present day occupational operations which may result in high levels of lead exposure and lead poisoning include: primary and secondary lead smelting, scrap metal handling, storage battery repair and manufacture, car radiator repair, crystal manufacturing, and ceramic production, to name a few. Other occupations in which workers can have high exposure to lead are: indoor firearms instruction, gunsmithing, typesetting, welding, and soldering. An investigation of lead disease among workers in two secondary lead smelters in Indianapolis, Indiana showed that among the women, there was a decreased rate of fertility, an increased rate of premature births, stillbirths, miscarriages and infant mortality. In men, altered spermatogenesis occurred even at low blood lead levels. In addition to these problems, the workers also experienced central nervous systems symptoms including tiredness, nervousness, fatigue and anxiety, as well as weight loss, muscle and joint pain and abdominal cramping (lead colic). The findings of this study conducted by scientists at the Mt. Sinai School of Medicine's Environmental Health Sciences Center provided essential information for the establishment of new exposure limits set by the Occupational Safety and Health Administration of the Department of Labor for workers in this industry. Other studies by scientists at the Mt. Sinai Center have identified similar symptoms among law enforcement officers and firearms instructors who spend long periods in indoor firing ranges. Their studies showed that of 81 law enforcement employees examined, more than half had elevated blood lead levels above 40 micrograms per 100 milliliters. To reduce the amounts of lead in the air at indoor ranges, Smith and Wesson has developed a nylon jacketed bullet. Lead ordinarily generated when firing a handgun was reduced in several tests from about 60 to 90% with the nylon jacketed bullet. Industry's cooperative response to the problem was ingenious and prompt.

At another of our Environmental Health Sciences Centers, New York University investigators found that the use of hair dyes increases the risk of breast cancer. The study suggested an increased risk of developing breast cancer if the women had used hair dyes for more than 10 years. In certain groups of women, hair dye use approximately doubled their risk of developing breast cancer.

Time lapse between exposure and manifestation of disease is also a factor in the development of asbestosis and mesothelioma. These diseases appeared, as I testified last year before this Committee, in some cases as late as 30 years or more after asbestos exposure.

These data suggest that exposures to environmental toxicants that are taking place today might not become manifest for many years; indeed if the exposure were to produce genetic damage, the consequences might only show up in our children or our grandchildren. We therefore have to be diligent as we continue our task of testing the tremendous backlog of untested or inadequately tested chemicals in our environment so that we can learn which are toxic, and then take steps to safeguard humans from those that are harmful.

Because of the suspicion that ethanol (alcohol) might act as a cofactor in vinyl chloride carcinogenicity, studies were conducted by the NIEHS-supported Center at the University of Cincinnati in which rats were administered 5% alcohol in drinking water prior to breeding and vinyl chloride exposure. Tumors were subsequently observed in 73% of male rats exposed to both alcohol and vinyl chloride while tumors were observed in only 31% of rats administered vinyl chloride alone. This indicates a synergistic effect between ingested ethanol and inhaled vinyl chloride in the induction of tumors.

Information from this Cincinnati study parallels findings from Mt. Sinai. The Cincinnati study indicates that occupational exposure to vinyl chloride produced more serious health problems if the exposed worker drank. In the Mt. Sinai study on asbestos workers, health risks were increased by cigarette smoking. This kind of research information provides the basis for effective prevention programs. For example, through education, those occupationally exposed to vinyl chloride or asbestos can significantly reduce their chance of disease if they abstain from alcohol or tobacco. Unfortunately, these precautions will not completely eliminate the excess risk these workers bear.

The research supported by the Institute has one primary goal: to prevent environmentally related disease. By identifying toxic substances, learning the mode of action within the body, determining at what level they are toxic to humans, and making this information available to those agencies responsible for regulation and education, the Institute fulfills its mission. The end product will be an increase in the quality of life not only for ourselves but for future generations as well. To perform these tasks, more scientists need to be trained.

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The need for trained manpower in the environmental health sciences has been recognized by this Committee and the NAS-NRC. Our budget request includes $2,000,000 to expand training programs in environmental toxicology.

Let me now turn to the National Toxicology Program which Secretary Califano established last November. The program provides for coordination and integration of the major toxicology programs within HEW. It includes components of the National Cancer Institute, the Food and Drug Administration, the National Institute for Occupational Safety and Health, and of the NIEHS.

Comprehensive toxicity tests of unstudied compounds to which major segments of the U.S. population are exposed will be the most obvious initial output of NTP. One objective of the NTP will be to test chemicals for the full range of toxic effects--possible damage to the nervous and endocrine systems, genetic mutations, birth defects, carcinogenesis, etc. As the program develops, its major contribution will be the development and validation of new and better integrated test methods. They will provide industry and the regulatory agencies with methods which will be much more efficient than we have today to test products before they are marketed.

Mr. Chairman, I have reviewed with you some of the major findings of the NIEHS during this past year and described programs that will in the future provide vital answers to several pressing environmental health questions. With your support we can continue this important work.

In conclusion, Mr. Chairman, the budget request for the National Institute of Environmental Health Sciences for 1980 is $79,012,000. I shall be pleased to answer any questions you might have.

SYNTHETIC ORGANIC CHEMICALS

Dr. RALL. Thank you very much, Mr. Chairman.

I would like to spend just a couple of moments describing the scope and extent of the scientific problems that NIEHS faces, and try to describe at least one example of where we think our research has been very cost-effective in terms of dollars and benefits to the public health.

We are concerned about potentially toxic environmental chemicals. I don't think most people realize the extent of the increase of production in the United States of synthetic organic chemicals in the last few decades.

In 1940, a little over 1 billion pounds a year were produced; in 1977, over 300 billion pounds a year were produced, an enormous increase.

That doesn't include such things as the effluents from combustion of fuel oil, coal and petroleum products, and raw materials such as asbestos.

The United States is a very large country, and we have a large population; but these numbers are very large, indeed.

It is estimated that 10,000 compounds a year are produced.

Our job is to search through those chemicals and identify those that are potentially toxic and that can cause harm to man.

ASBESTOS

Now let me use asbestos as one example of this.

As early as 1967 NIEHS began supporting studies of the human health effects of asbestos. Our grantees were able to show an enormous toll from asbestos exposure—lung cancer, a variety of other cancers of the chest and abdomen, and a type of pulmonary fibrosis, called asbestosis.

The data from the studies supported by these grants were used when the Occupational Safety and Health Administration set standards for asbestos exposure in the work place, in 1972 and in 1976.

Before 1972, asbestos was essentially uncontrolled. About 33 percent of asbestos workers died prematurely of asbestos induced disease.

Using information from our grantees, meaningful standards were set in 1972 and revised 1976. It is our estimate that the application of these standards will save about 10,000 lives a year over the next 35 to 40 years.

This, I think, is a major public health achievement, due to the effective regulatory use of research findings developed by NIEHS and other NIH institutes.

NATIONAL TOXICOLOGY PROGRAM

Dr. Fredrickson and Dr. Upton described the National Toxicology Program, which is a new initiative this year. The program pulls together the research and toxicity testing of substances throughout HEW, and organizes it into a single coordinated program. It pools the relevant activities of the National Cancer Institute, the Food and Drug Administration, the National Institute of Occupational Safety and Health, and the National Institute of Environmental Health Sciences.

This activity is advised—and this is an important feature—by the four major regulators, the Environmental Protection Agency, Occupational Health and Safety Administration, Consumer Product Safety Commission, and Food and Drug Administration.

Chairman Magnuson asked yesterday whether this led to duplication. In fact, it is the only sure way to avoid duplication. By having the regulatory agencies and the research agencies planning together, we assure that the very best research is done, and that the research that is most responsive to the needs of the regulatory agencies is performed.

Thank you, Mr. Chairman. I will end my brief remarks.

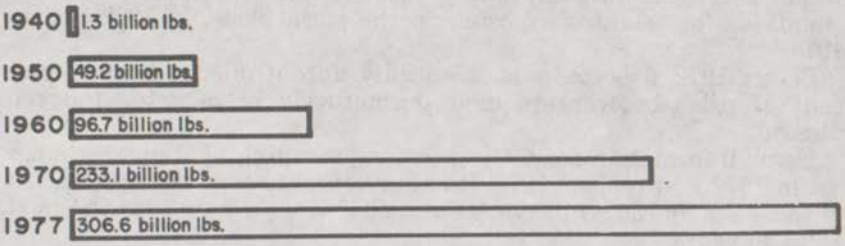
Senator HATFIELD. All right.

PRODUCTION OF ORGANIC CHEMICALS, MINERALS, AND FUELS

Dr. Rall, have you a breakdown on—first of all, let me see if I understand these charts again. This is the production record that you have provided us?

[The charts follow:]

U.S. PRODUCTION OF SYNTHETIC ORGANIC CHEMICALS



Source: U.S. International Trade Commission

TOTAL U. S. PRODUCTION OF ORGANIC CHEMICALS, MINERALS, AND FUELS
1977

● Synthetic organic chemicals manufactured	153 million tons
● Asbestos used (as a raw material)	700 thousand tons
● Fossil fuel combustion	
Coal	630 million tons
Petroleum products	5.9 billion barrels

USE CATEGORIES

Dr. RALL. Yes.

Senator HATFIELD. Now, can you break that down into the use categories, or the categories to which this is put, like agriculture, or industry?

Dr. RALL. I will be happy to supply such information for the record.

[The information follows:]

U.S. use of synthetic organic chemicals—1970

	Billions of pounds
I. Industrial use—Raw materials used in production of finished products:	
A. Crude products from petroleum, natural gas, and coal tars	89.0
B. Cyclic intermediates	28.3
C. Organic pigments	.2
D. Plastics and resins	24.5
E. Plasticizers	1.3
F. Rubber processing chemicals	.3
Subtotal	143.6
II. Agricultural use: A. Pesticides and herbicides	1.6
III. Consumer use:	
A. Surface-active agents (detergents)	3.9
B. Flavors and perfumes	.1
C. Medicinal chemicals	.2
D. Synthetic rubber	4.4
Subtotal	8.6
IV. Mixed uses: A. Finished chemical products (solvents, alcohols, photographic chemical, et cetera)	79.3
Total	233.1

2,4,5–T AND 2,4–D

Senator HATFIELD. In other words, we have 306.6 billion pounds. Where is it used? And the tons over here, where is this used?

This morning at 9 o'clock, EPA announced the suspension of the herbicide 2,4,5–T which is used in forestry management. And based on a study they made near Alsea, Oreg., of miscarriages over a 6-year period, they have related it to the proximity of the use of this herbicide.

Do you have any comment on that?

Dr. RALL. Our Environmental Health Sciences Center at Corvallis has been actively involved in this study. Much of our intramural research work has been involved in the toxicity of dioxins TCDD. I think the scientific consensus is that 2,4,5–T itself is relatively safe, but it is essentially impossible to manufacture without making dioxin and dioxin is exceedingly toxic. It persists in the environment for long periods of time, and this, is the problem.

We have been studying the problem of herbicides contaminated with dioxins for the past several years. Human health problems have been a concern for a long time certainly with regard to Vietnam.

Senator HATFIELD. You mean as part of the defoliation program?

Dr. RALL. Yes sir. We are hoping that the herbicide 2,4–D will be a much more safe and adequate substitute.

Epidemiologists from our Center at Mount Sinai School of Medicine working with our Center at Corvallis, are looking at some of the lumberjacks in Oregon to see whether we can detect any adverse effects in adults exposed to 2,4,5–T.

ASBESTOS

Senator HATFIELD. Dr. Rall, you made special comment in the area of asbestos.

As you know, during the past year, Secretary Califano has made a major effort to warn the American public about the dangers of exposure to asbestos.

What role does your institute play, and what still must be done in this warning system?

Dr. RALL. Dr. Upton and I are cochairmen of the informal group Secretary Califano put together for that program. Both NCI and NIEHS have been deeply involved over the last 10 years in trying first to identify the nature of this very complex problem; and second in trying to identify the dose response curve; how much asbestos can the human population stand without unreasonable extra risk.

This is a very difficult task on which we are just now embarking.

Senator HATFIELD. Where is the money coming from to fund this kind of activity?

Dr. RALL. From the regular budget that you have before you of NIEHS, and of NCI.

Senator HATFIELD. You've done this without the call for supplementals?

Dr. RALL. That is right.

Senator HATFIELD. In this warning system and so forth, how effective can you hope to make it? Based upon an account I would like to share with you of a friend, who is today being treated with chemotherapy for cancer of the chest lining, and the diagnosis seems to lead to the fact that 30 years ago this person was working in asbestos, but has not been for the last 30 years.

Now, is there this kind of dormant carrying of the problem? It does manifest itself in a long period of time?

Dr. RALL. The latent period can be up to 35 or 40 years. There was a recent article from South Africa involving 70 patients with mesothelioma—cancer of the chest lining—none of whom worked in asbestos factories. They were carefully questioned about their life history. Sixty-nine out of the seventy had sometime in the past—through some ancillary work experience—been exposed to asbestos.

Since World War II, between 8 and 11 million people in this country have at one time or another worked with asbestos. Of course, Secretary Califano was most concerned about former shipyard workers who were exposed to asbestos insulation in shipyards 30–40 years ago. This situation is a public health disaster.

SMOKING AND HEALTH

Senator HATFIELD. The last year's committee report directed you, I believe, to use a portion of your increased funding for additional research in the area of smoking and health; is that correct?

Dr. RALL. Mr. Lierman says yes. It did not appear in conference.

Senator HATFIELD. Would you give us that for the record?

Dr. RALL. Yes, sir.

Senator HATFIELD. As of now.

[The information follows:]

STUDIES ON SMOKING

In its report on the 1979 appropriation bill, the Senate Appropriations Subcommittee stated that it expected "the Institute to use a portion of its increase [over the President's request] for additional research efforts in the area of smoking and health." Similar directive language is missing from the conference report.

NIEHS is concerned with the relationship between smoking and exposure to other toxic agents in the environment in the development of disease in humans. For example, the likelihood of developing lung disease following exposure to asbestos is 30 times greater for people who smoke than for people who do not—assuming all are subject to the same exposure. Therefore, NIEHS is primarily concerned with tobacco smoke as an agent which may affect people's risks from exposure to other toxic substances.

The Institute is currently supporting 24 projects which will total approximately $1.1 million in 1979. It has increased its budget in smoking and health approximately 10 percent in 1979 and 1980.

The Institute supports 3 research projects dealing solely with tobacco constituents or directly with smoking per se on health. One of these 3 projects deals with carbon monoxide in cigarette smoke and its relation to carboxyhemoglobin in the blood. One attempts to relate polonium-210, a radioactive isotope, in cigarette smoke to that in the lungs of smokers. The third project is concerned with identification of carcinogens and cocarcinogens in cigarette smoke. These three projects represent a relatively small portion of the NIEHS smoking and health budget.

The major effort involving tobacco is concerned with smoking as one parameter in the health effects of general air pollutants and gasious and particulate substances in the occupational environment. Some 21 projects are focused in these areas. Major efforts concern specific substances, for example sulphur dioxide. Polonium-210 and various particulates, particularly asbestos. Other studies focus primarily on the effects, or endpoints, of exposure to combinations of pollutants and tobacco smoke. Such studies deal, for example, with prenatal toxicity of carbon monoxide, effects on gastrointestinal and pulmonary functions, role of mixtures of pollutants and smoking in the development of obstructive lung diseases, epidemiological aspects of smoking and air pollution, and finally the influence of smoking on lung cancer, mesothelioma, and asbestosis in asbestos miners, insulation workers, and the families of asbestos workers.

The program planning workgroup report now in final preparation recognizes the importance of smoking in relation to environmentally-related diseases and disorders. The will state that NIEHS should continue its interest in the relationship of tobacco smoking to ill-health, particularly in research on the interaction of smoking with other toxic agents in the environment. Studies of the relationship of other environmental agent to chronic respiratory disease or bronchial carcinoma will usually be of questionable value if the confounding effects of cigarette smoking are not taken into account.

NIEHS intends to implement these recommendations in order to further define the role and mechanisms of tobacco smoke in the induction and ehancement of cancer, heart and lung disease, and other types of diseases induced by gaseous and particulate air pollutants.

NATIONAL TOXICOLOGY PROGRAM

Senator HATFIELD. You mentioned a while ago of being jointly associated with Dr. Upton. What programs, other programs are you and Dr. Upton joining in, in terms of developing, and how much funding switches hands between the various institutes to help on these programs?

Dr. RALL. Between NIEHS and NCI, there has been no transfer of funds. We work together, very closely, and we jointly fund some projects when we see a common problem.

Senator HATFIELD. There is no transfer of funds?

Dr. RALL. No sir. But with the national toxicology program, which is a major new effort, there is now consolidated $10 million from NIEHS and more than $21 million from NCI, plus contributions from two other HEW agencies, in what is an integrated

program to search out toxic substances and to develop better methods for testing. This latter we think is most important.

Dr. UPTON. Could I comment, please, Mr. Chairman, on this particular program?

Senator HATFIELD. Please do.

Dr. UPTON. As I mentioned yesterday, I think we are fortunate to have the program in place now. It does provide for systematic cooperation and coordination between NCI, NIEHS, FDA, and NIOSH; and it does reach out and include the other regulatory agencies, as Dr. Rall mentioned.

Our bioassay program has been put lock, stock, and barrel into the national toxicology program. We funded the program last year at about $18 million. We went into this year projecting about $21 or $22 million.

It turns out now that to sustain the input of compounds that need to be tested we are probably going to have to operate at a level closer to $27 million this year, and the projection for next year is about $34 million, simply to stand still.

So, we are facing, with this commitment, a large increase in costs, standstill costs.

I mentioned this because I think it is an extremely important allocation of funds to a national need. It does represent a tangible contribution by the National Cancer Institute to this interagency program, and I am pleased that we are working with Dr. Rall, and that he is directing the program. I feel confident that the country is getting a good return for its dollar.

Senator HATFIELD. You are at the same level, approximately, of financing that you were last year?

Dr. UPTON. Yes. We must meet this expanding demand without a commensurate increase in resources. We will have to do what we can in the program.

OCCUPATIONAL HAZARDS

Senator HATFIELD. Let's turn to this, if I can—and this is the last question; and perhaps Dr. Upton might want to answer this. That relates to occupational hazards in the work place, as they are related to cancer.

Would you review briefly what you are doing in this area, and what you perceive the program should actually do?

Dr. RALL. Approximately one-third of our budget is devoted to research related to occupational exposures. Specifically, we are convinced that the exposure to carcinogenic agents in the work place is a major problem. We think the previous estimates, that only 1 to 5 percent of cancer is due to occupational exposure are unrealistically low. We suggest that the estimate should be close to 20 percent.

We at NIEHS are not specifically charged with occupational health, but most chemicals appear both in the work place and in the environment, and our research on better testing methods and on testing chemicals for toxicity is applicable both to the specific environments such as work places as well as the broader environmental context.

Our work is with a variety of toxic agents, compounds that are manufactured and found in the environment. When we discover toxic effects, we pass this information to both NIOSH and to the Occupational Safety and Health Administration.

OCCUPATIONAL CARCINOGENESIS

Dr. UPTON. To comment for NCI, Mr. Chairman, we see the needs for and opportunity for research on occupational risk factors for cancer to be very real today.

I would point out that from 1976 through 1980 our budget has increased substantially. We project a 110 percent increase in the allocation to occupational carcinogenesis over this period.

Our focus, of course, is on the cancer risk; and Dr. Rall's institute is looking at broader risks: effects on the nervous system, effects on the kidney, and other kinds of end points.

COORDINATION WITH OSHA

We are cooperating with the National Institute for Occupational Safety and Health, funding roughly $4 million of joint projects with that institute; and I can provide a list of those projects for the record, if you wish.

[The information follows:]

LIST OF NIOSH PROJECTS

1. Kepone registry
2. Cancer surveillance of occupational cohorts in a western SMSA.
3. Mortality and industrial hygiene study of styrene-Butadine rubber workers.
4. Mortality medical and industrial hygiene study of polychlorinated biphenyls.
5. Mortality and industrial hygiene study of perchlorethylene workers (dry cleaners).
6. Mortality, medical, and industrial hygiene study of chlorinated hydrocarbons.
7. Industrial hygiene and medical study of workers exposed to azo dyes.
8. Mortality, medical, and industrial hygiene study of the painting trades.
9. Mortality and industrial hygiene study of printing trades.
10. Mortality and industrial hygiene study of phosphate workers.
11. Mortality and industrial hygiene study of nitrosamines/cutting oil.
12. Mortality study of beryllium workers.
13. Morbidity and IH study of fibrous mineral workers.
14. Develop behavorial approaches for improving work practices directed toward reducing occupational exposure to carcinogens.
15. Perform intratracheal testing of copper and lead smelter dusts and fractionated smelter dusts to determine their carcinogenicity.
16. Sulfur dioxide effect on smelter dust carcinogenesis.
17. Identification of high risks industries for cancer.
18. Mortality by occupation and industry.
19. Mortality and industrial hygiene study of new agents–III.
20. Develop protective equipment for carcinogens.
21. Metabolism of azo dyes to carcinogenic amines.
22. Chronic inhalation of short asbestos.
23. Foundry mold sand pyrolysis effluent—Carcinogenesis.
24. Roofing asphalts and UVL carcinogenesis.
25. National occupational hazard survey-data base development, analysis and access.
26. Mortality, medical, and industrial hygiene study of talc workers.
27. Mortality and industrial hygiene study of workers exposed to styrene.
28. Industrial hygiene study of new agents–II.
29. Mortality and industrial hygiene study of goldminers.
30. Mortality, morbidity and industrial hygiene study of brake lining workers.
31. Mortality and industrial hygiene of benzene workers.
32. Mortality and industrial hygiene of foundry industries.

33. Mortality study of workers in the plywood, paper, and pulp industry.
34. Mortality study of pesticide formulators.
35. Determine whether thallium trioxide and antimony trioxide are carcinogenic in animals.
36. Carcinogenicity of inhaled 1,2-dibromoethane.
37. Bioassay of cutting oils containing nitrosamines.
38. Development of a national sample frame for hazard surveillance.
39. Linkage of NOHS and RTECS.
40. Development of trade name ingredient data base.
41. Mortality, medical, industrial hygiene study of workers exposed to ethylene oxide.
42. Medical and industrial hygiene study of workers exposed to polybrominated biphenyls.
43. Mortality and industrial hygiene study of workers exposed to acrylonitrile.
44. Mortality study of crushed-stone exposure.
45. Tumorigenicity of nitroaliphatics..

CORRELATION OF ACTIVITIES WITH OSHA

Senator HATFIELD. How do you correlate these activities to the OSHA program in the Department of Labor?

Dr. RALL. OSHA participates in the planning and governance of the national toxicology program.

Yesterday morning before our hearing, Dr. Upton and I and the Assistant Secretary of Labor for OSHA met for an hour and a half on the problem of what chemicals should we enter into the national toxicology program testing for this current year. This is a very direct and straightforward cooperation and information exchange OSHA says: Here is what we need. We say: Here is what we can do.

Dr. Fredrickson said yesterday, this is a major achievement.

[The information follows:]

POSSIBLE DUPLICATION

Question: Part of the role of the Environmental Institute is to develop test methods for determining the toxicity of substances. The Environmental Protection Agency, the Food and Drug Administration, the Occupational Safety and Health Administration, the National Institute for Occupational Safety and Health, and the Consumer Product Safety Commission, as well as the Cancer Institute, and some other Federal agencies are also responsible in the area of environmental programs. With so many, Dr. Rall, just how do you coordinate all of your efforts?

Answer: We feel coordination is quite important. Our resources are limited and our responsibility is broad, so we at NIEHS are especially careful to avoid unnecessary overlap and duplication, and to communicate with and coordinate with scientists at other agencies.

We have discussed the DHEW Committee to Coordinate Toxicology and Related Programs. It has proven most helpful and effective.

The National Toxicology Program will manage the significant efforts to improve test methodology and conduct chemical toxicity tests efficiently.

Question: Is there any way you can assure us that there is no duplication of effort in any of these areas?

Answer: I personally cannot assure the committee that there is no duplication of effort per se. However, we are represented on most of the major coordinating groups in the area of environmental health research. Thus, I can assure you that NIEHS is most careful to identify and avoid unnecessary duplication of effort on its part; and I believe that, when it is fully functional, the National Toxicology Program will enhance this.

Question: Please give us some specific example of how you have been able to offer these regulatory agencies assistance in the past year and to help them test suspect substances.

Answer: Over the past year NIEHS has made some important contributions to the identification and control of hazards to health in the environment. Its research on the metabolism and pharmacokinetics of chlorinated hydrocarbon chemicals has been critical to the control of highly toxic pesticides, industrial chemicals such as the polychlorinated biphenyls, and the highly toxic impurities such as dioxins and furans which occur in many industrial products such as pesticides, hexachlorophene, and pentachlorophenol. This research has also enabled the Institute to respond to and alert other public agencies to the dangers and hazards from accidental exposures such as the incident involving general contamination of food supplies by polybrominated biphenyls in Michigan.

Beyond these specific examples, the action which was taken that is of most importance to the regulatory agencies is undoubtedly the establishment of the National Toxicology Program. This program, which joins the efforts of the regulatory and research agencies, will provide much needed data regarding the toxicity of chemicals jointly selected for testing.

FUNDING FOR TOXICOLOGY PROGRAM

Question: It appears that for at least the first year the National Toxicology Program will be funded by "rerouting funds" from the various agencies involved in the program. Do you expect that any of your funds will be used for this program?

Answer: The National Institute of Environmental Health Sciences has agreed to furnish approximately $10.2 million to the National Toxicology Program in Fiscal Year 1979. Approximately 60 percent of these funds will support ongoing NIEHS activities which respond to the program's plan. The balance will be available to support research and test development activities prescribed in the plan. This total amount will increase to approximately $10.8 million at the President's budget level in 1980.

Question: If so, do you plan to send a reprogramming request to the Committee?

Answer: At this time we believe that we can support these activities with our FY 1979 and 1980 budget plans, and no reprogramming request will be submitted.

Question: How much in FY 1980 will you be spending in this area?

Answer: At the level of the President's budget request, NIEHS will be devoting approximately $10.8 million to the National Toxicology Program.

MAGNITUDE OF CHEMICAL EXPOSURE

Question: The National Toxicology Program was established in November 1978 to, I understand, strengthen HEW's activities in the testing of chemicals of public health concern as well as in the development and validation of new and better test methods. How many chemicals do we presently have available in American society today?

Answer: Estimates vary, but we feel there are over 60,000 compounds or substances in commerce today, of which about 10,000 are produced in quantities over one ton each.

Question: How many new ones are developed every year?

Answer: We are not sure, but we believe that up to about 1,000 new compounds enter into commerce each year. Of this total, about 100 to 150 new chemical are produced in significantly large quantities. At this time, however, it is not known how many chemicals go out of production each year.

Question: Are every one of these tested before they are put on the marketplace?

Answer: When the toxic substances control act is implemented, EPA will decide which of these new chemicals will require toxicity testing before they can enter commercial markets. Currently only drugs must be fully tested before marketing.

NEW FACILITY

Question: Dr. Rall, your new building down in the Research Triangle which houses the Institute should be done in the near future, I think. What is your completion date and what reports do you have for the Committee on progress so far?

Answer: I am pleased to report, Mr. Chairman, that progress on the construction of the new facility is coming along well. The contractors should complete the warehouse and shop buildings in our support area this summer, and we hope the laboratory and office building will be completed by late 1980 or early 1981.

Question: Given a budget request that the very least provides only about $800,000 over last year's level, how will this allow you to buy the equipment and fund the personnel necessary to maintain the new facility and operate it at maximum use?

Answer: In 1977 we submitted a report to the Committee specifying our requirements to develop and operate this facility. It was determined that $17.2 million would be needed for equipment, and that $3.3 million would be required in 1980 for recurring operational costs. Of the $17.2 million equipment requirement, $9.5 million is for basic operating equipment and furnishings; and the remainder is for laboratory apparatus. Operational costs would provide for utilities, security and contractual services; and for an increase of 109 government employees for central service activities.

The 1979 Appropriation provides $2.4 million to begin to equip the new complex. The same amount is available in 1980, bringing the total allocation to $4.8 million. During FY 1980 we will occupy support services buildings and assume responsibility for their operation. Funds and positions will be made available from intramural research projects in order to adequately meet this requirement. The remainder of the equipment must be purchased from fiscal 1981 and subsequent years' funds. Utilization of the entire facility will not be possible until construction is completed early in FY 1981.

Dr. UPTON. We have maintained a very close, informal cooperation with OSHA, but I think with the formalization of the relationships, and with the national toxicology program, we can expect closer coordination.

Senator HATFIELD. Thank you very much. I would like to inject a question at this point, Dr. Upton, that I am particularly interested in, and that relates to the matter of vitamin C.

Dr. UPTON. Yes.

Senator HATFIELD. First I would like to make a reference to the proceedings of the National Academy of Sciences, September 1978, a statement made by Dr. Jules A. Comroe, Jr., University of California, San Francisco, when he stated that cancer is a serious problem in every physician, and biomedical scientists must surely welcome new ideas, concepts, and approaches that might hasten solution of the problem.

The 1976 paper by Dr. Pauling presents such a new approach.

What has the National Cancer Institute done to examine this specific new approach?—treatment of cancer by the administration of massive doses of vitamin C, and as you know, new programs are now underway, or new tests are being made now in Los Angeles about combining not only massive doses of vitamin C, but also combining that now with a dietary approach.

The National Cancer Institute, as I understand it, set up new programs on nutrition in cancer. Applicants complain that the existing study sections consist of people whose main interest is in other fields and who downgrade innovative applications.

Are you setting up a special study section for these new programs, and I might just comment further that I have had opportunity to talk to cancer experts, surgeons particularly, as well as chemotherapists in different parts of the country, and the general reaction I get from any one of them when I raise this particular issue is an immediate brushoff, that this is unproven, that this is not relevant, it has no value whatsoever.

In a followup question to these same physicians, "Have you made any study of it, or have you made a judgment evaluation," well, the answer is "no."

It is almost like some colleagues in my political party when you ask them a question. They have predetermined views, that they can't accommodate to any kind of approach, that is, the right one.

But I'm just interested in knowing your view and how this is being reacted to, or responded to, whichever the case may be.

Dr. UPTON. Thank you, Mr. Chairman.

There are very few people in the world who have attained greater distinction in science than Dr. Linus Pauling, and he has in fact received support from the National Cancer Institute in the past.

It is true that he is not receiving support at the present time, and that several grant applications he has submitted to NIH to pursue his ideas on vitamin C have not qualified for funding.

It turns out he has submitted since 1973 five applications, and the five have been reviewed by four different study sections outside of the National Cancer Institute. These are study sections under the Division of Research Grants, which should be objective, inter-

ested, and unbiased. The priority score, that is the measure of the quality of the applications as judged by those study sections, has not been high enough to allow the funding of Dr. Pauling's grants.

I have met with Dr. Pauling, we have discussed this. I don't think that one can discredit his ideas. I think the problem is the presentation of those ideas, and the design of experiments with which he has sought to test them.

It turns out that the ideas are being tested by others. The National Cancer Institute is supporting a clinical trial at the Mayo Clinic with Dr. Moertel, in which one group of patients will receive vitamin C, and a control group of patients will not receive vitamin C. This study will allow one to determine whether the initial results published by Pauling can be corroborated. There are problems with regard to the initial study with respect to adequacy of controls.

In the Moertel experiment, very strict control and precautions have been taken.

All in all, we are now supporting about $900,000 worth of research on vitamin C in the Cancer Institute, and the projection is to increase that for 1980, despite the fact that our budget will not go up.

The research ranges over a wide variety of subjects. We mentioned Dr. Moertel's clinical trial, using vitamin C in the management of patients with cancer.

There is another double-blind clinical trial being conducted at St. Mark's Hospital in London, in which patients with polyposis of the colon, predisposing them to cancer of the bowel, are given vitamin C to determine whether vitamin C would retard or inhibit the evolution of cancer.

Senator HATFIELD. That is the Morson project?

Dr. UPTON. Yes, with very strict controls, so the results should be definitive and reliable.

A wide variety of experiments are being done in animal systems, where there is good evidence that vitamin C can interfere with the activation of particularly cancer-forming compounds, nitrosamine, for example. It seems to reduce the concentration of mutagenic material in the large bowels of test animals.

So there are a number of reasons why this subject deserves careful and systematic investigation, and we are doing everything we can to support such studies. However, we can only support those applications which are found by peer review to warrant support.

I have urged Dr. Pauling to resubmit, and I would hope that he would do so. As to the study sections, we are assured by the Division of Research Grants that they will make special efforts to see that study sections are constituted in a way that allows them to be critical, and yet objective and fair, with regard to applications relating to vitamin C. They will set up special study sections, if need be.

In the Cancer Institute, we are considering the chartering of a new committee to further assure that this kind of objective and receptive attention is given.

Senator HATFIELD. Thank you, Dr. Upton.

Dr. Upton, the grant given to Dr. Pauling, did it relate to vitamin C?

Dr. UPTON. I will have to check that for the record, Mr. Chairman.

Senator HATFIELD. I am told that it did not.

Dr. UPTON. I will have to check that for the record.

Senator HATFIELD. Also, would you check for the record, I understand that other than the Basil Morson project at St. Mark's in London, that not more than 10 percent of the grants that are made in relation to the 900,000 figure that you related there to vitamin C research, not more than 10 percent of these other grants actually relate to vitamin C. Rather vitamin C is incidental to the grant.

Now, whether that is valid or not, I would like to have you check those grants and let us know. The figures is very impressive.

But as I understand the thrust of the grant, it is other than vitamin C.

Dr. UPTON. We will certainly be happy to provide the detailed breakdown for the record.

[The information follows:]

Grant Award to Dr. Linus Pauling

Dr. Linus Pauling has received one grant award from the National Cancer Institute. The award ran from June 1, 1975 through May 31, 1977. This grant did not deal with vitamin C. Its title was "The Orthomolecular Diagnosis of Cancer."

Vitamin C Research

Vitamin C research at the National Cancer Institute totaled approximately $865,000 in fiscal year 1978, with estimated totals of $900,000 and $925,000 for fiscal years 1979 and 1980, respectively. There are 20 grants which include research on vitamin C, and the dollar portions of those grants pertaining to vitamin C have been included in the overall amounts for 1979 and 1980. Only one of these grants has more than 10 percent of their effort devoted to vitamin C research.

At the present time there is one research grant funded by NCI which is totally devoted to vitamin C research. This is being carried out at St. Mark's Hospital in London, England. The grant is entitled "Randomized Trial of an Antioxidant in Polyposis Coli." It is a double-blind study, with neither the doctor nor the patient knowing if the active drug (vitamin C) or a placebo is being used. *Polyposis coli* is a genetic disease of the large bowel involving multiple tumors which are sometimes reversible before malignancy occurs. It is hoped that this study can be used as a model for further study of cancers of the large bowel.

There is also a contract funded by NCI for vitamin C research through a clinical trial at the Mayo Clinic with Dr. Moertel. This is a double-blind study with patients with gastrointestinal cancer in which one group of patients receives vitamin C and the other receives a placebo. The purpose of the study is to demonstrate whether vitamin C improves the quality of life or prolongs the life of patients with otherwise untreatable cancer.

Also in the area of cancer treatment, several studies are underway to: Determine the effectiveness of vitamin C in relieving symptoms and extending the lives of patients with advanced and preterminal cancer; to evaluate new treatments for patients with metastatic nonsmall cell lung cancer; and to determine if vitamin C enhances antitumor activity of certain other agents.

NUTRITION RESEARCH

Dr. UPTON. I would like to mention that, as I stressed yesterday, we sought to increase our effort in nutrition research, and we have issued program announcements, requests for applications, which to date seemed to have been answered enthusiastically. We would

expect to be able to report at future hearings that the level of effort will have been increased.

LAETRILE

Senator HATFIELD. Would you permit me now to step out further on thin ice and ask you to provide for the record what you have done in evaluating and assessing laetrile in its treatment for cancer?

Dr. UPTON. I should be happy to do that, Mr. Chairman.

[The information follows:]

EVALUATING AND ASSESSING LAETRILE

During 1978 the National Cancer Institute initiated and completed a retrospective study of the drug Laetrile (amygdalin). The results of this study were summarized in the New England Journal of Medicine. On September 25, 1978 the Decision Network Committee of the Division of Cancer Treatment met to consider the clinical data provided by this analysis. The recommendation of this committee was to initiate a prospective phase II (testing for tumor specificity) evaluation of this drug as part of the Division's drug development program. On December 15, 1978 a notice of claimed investigational exemption for a new drug (IND) with the substances DL-Amygdalin (NSC 251222) and D-Amygdalin (NSC 15780) was filed with the Food and Drug Administration. On January 15, 1979 the National Cancer Institute was notified by the Food and Drug Administration that there were questions regarding the chemistry section of the document submitted. The NCI staff is responding to these questions. When these issues have been sufficiently clarified, the National Cancer Institute will proceed with the phase II evaluation of this drug. It is anticipated that this prospective phase II study will take approximately 1 year to complete. No assessment about laetrile's alleged cancer curative properties can be made at this time.

ADVERTISING AND RESEARCH

Senator HATFIELD. And what you are doing now in terms of advertising, or research.

Dr. UPTON. Mr. Chairman, as you know, there have been repeated efforts in experimental animals to assess the efficacy of laetrile as an anticancer agent, and these have led to negative results.

There have been occasional suggestions of an effect, but attempts to reproduce them have not succeeded.

We have proposed a clinical trial of laetrile, and have submitted an IND application to the Food and Drug Administration, which is now considering that application. It had been my hope that we would have the application approved and have a trial underway by now.

I have no reason to suppose the approval won't be forthcoming, and that the trial will not get underway. But in a nutshell, that is the status of the matter. We have not thought that it would be reasonable to reinvest in animal studies. There seems to have been many of those.

We have thought that the experience to date justified a trial. There are said to be tens of thousands of patients receiving laetrile in the private sector. Some of the patients on other drugs have been receiving laetrile on the side. There has been an enormous public desire to have this issue clarified.

We are told that patients will willingly give informed consent to receive laetrile. Thus, the ethical issue does not stand in the way.

We would not perform a trial to prove that laetrile was ineffective. This would be unjustified. But there is evidence, albeit inconclusive, to suggest that there may be a benefit, and I think we are

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willing to take the step to determine whether that benefit can be shown.

Senator HATFIELD. The staff has just informed me that I have just fallen in. Only an impressionable member of this committee would do that.

I would like to say that I don't think that legislative boards are places to resolve a medical question, such as those State legislatures that have enacted specific laws to permit the use of laetrile within the confines of those States. But I do feel that some of that has been as a result of the failure on the part of medical scientific research to give careful review and make proper testing on this subject.

And as a consequence, there is a lot of emotion in this on both sides of the picture.

Dr. UPTON. I can assure you, Mr. Chairman, that I have received an avalanche of letters displaying very divided opinions. The scientific community is split down the middle. The profession is divided.

So depending on which camp you belong to, you can get very strong advice, pro and con.

I think that our decision to propose the trial and conduct a trial was reached only after an enormous soul-searching.

Senator HATFIELD. When does the trial commence?

Dr. UPTON. We are poised and ready to begin as soon as the Food and Drug Administration grants its approval.

Senator HATFIELD. What is the time frame that you estimate?

Dr. UPTON. We would estimate that within 6 months after we get underway, we should have evidence whether or not laetrile produces a therapeutic effect.

CANCER DRUGS

Senator HATFIELD. What is this Houston drug that has been experimented with?

Dr. UPTON. There are two drugs that have received attention in Houston within the past 6 months, thymidine and interferon. Both of them are naturally occurring substances, and both of them were thought to be relatively nontoxic.

There is an enormous interest, therefore, in determining if they are anticancer agents. Each of them has shown some evidence in animal tests that they can inhibit the growth of tumors in experimental animals.

Today, the human evidence is very inconclusive and fragmentary. We are conducting trials on both compounds. Again, within 6 months, I should think we would be in a position to make a more substantial assessment.

Senator HATFIELD. I was given this following count, and I would like to have you comment on it. That approval was given by FDA for the use of this in the Houston facility, and they suggested that the number be restricted to 12, that the drug, or the chemical be manufactured in the State of Texas.

But in the permit or the approval given by FDA, they required the import of this particular chemical from, I believe, West Germany, and had to go through a various process of being reprocessed once it arrived in the United States, which has created a tremen-

dous delay in the availability; further that the facility has the capability of testing this on 200 patients, rather than only 12, and are willing to do so, but for the lack of the chemical.

It appears to me that if it is permitted to be tested on a human being, under the wisdom of the FDA, why the arbitrary figure of 12, rather than being able to develop a broader base from which one can make judgments in testing, and fulfill the capability of the facility that can treat 200.

Dr. UPTON. The circumstances under which INDS are granted can vary, depending on the special conditions at hand.

It turns out now that we are in a position to test both thymidine and interferon on a much broader base, and the supply of interferon is limiting. The bulk of it comes from Scandinavian countries. But the supply of thymidine is not limited. It appeared to be limited at the outset, but it is no longer limited.

So, I think that one can expect, within 6 months, as I indicated, some clarification of the value of both of these two substances.

Senator HATFIELD. How much will you plan on budgeting, or spending on this, within, say, 1979 and 1980?

Dr. UPTON. I'll have to provide that information for the record, Mr. Chairman. I don't have the figures at my fingertips.

Senator HATFIELD. Thank you.

[The information follows:]

THYMIDINE

Thymidine is a natural constituent of the body. In large doses, there is experimental evidence that it may function as an anticancer agent. We have purchased large quanitites of thymidine in fiscal year 1979 at an estimated amount of $1,737,000. A clinical trial is underway and the estimated cost is $60,000. Plans for fiscal year 1980 will depend upon the results of the clinical trial which is expected to be complete in late fiscal year 1979.

Research and production of thymidine

	Fiscal year 1979 estimate
Drug purchases	$1,737,000
Drug research (screening/toxicology)	61,000
Clinical trials—conducted at:	
Baltimore cancer research program	10,000
Sloan-Kettering Institute for Cancer Research	25,000
Sidney Farber Cancer Center	25,000
Subtotal	60,000
Total	1,858,000

INTERFERON

Interferon is an interesting antiviral material which can be produced by the body under appropriate stimuli. It is one among several biological response modifiers that are under review for their application to the treatment of cancer. More specifically, NCI has initiatd a sources sought advertisement to determine the availability of large quantities of interferon. Once qualified suppliers have been identified, an advertisement will be issued to request bids for a competitive procurement. A clinical trial is under consideration for late fiscal year 1979 or early fiscal year 1980.

RESEARCH AND PRODUCTION OF INTERFERON BY FISCAL YEAR

	1979	1980
Drug purchases	$1,500,000	.....
Drug research (screening/toxicology)	5,000	.....
Drug production	200,000	$200,000
Clinical trial	100,000	500,000
Grant supported studies	308,000	310,000
Total	2,113,000	1,010,000

Senator HATFIELD. Could I turn to Dr. Tower for a moment? Dr. Tower, I would like to go into a little bit on the matter of the National Institute of Neurological and Communicative Disorder and Stroke, NINCDS. For the record, what was the total amount of funds spent on spinal cord regeneration research in fiscal 1976, 1977, 1978 and up to 1979?

Dr. TOWER. For regeneration research for 1976, $1.97 million; 1977, $3.15 million; 1978, $5.934 million; and we estimate for this year, 1979, $6.9 million.

Senator HATFIELD. Thank you. What was the total amount spent with direct application on chronic spinal cord regeneration research for the same years, 1976–1977?

Dr. TOWER. I misunderstood your question. That is the total amount. I would have to get a breakdown.

Senator HATFIELD. Would you get a breakdown for acute and the chronic? That is really what I'm trying to break down.

Dr. TOWER. Yes, sir.

[The information follows:]

NINCDS SPINAL CORD REGENERATION RESEARCH

	Acute spinal cord regeneration	Chronic spinal cord regeneration	Total
1976	$1,374,000	$596,000	$1,970,000
1977	2,195,000	955,000	3,150,000
1978	4,098,000	1,836,000	5,934,000
1979 proposed	4,705,000	2,195,000	6,900,000

Senator HATFIELD. Dr. Tower, in your testimony before this subcommittee in 1977, you indicated that you could effectively spend an additional $6 million over and above the level of expenditures for regeneration research. That is, if this sum were provided by Congress.

The language of the Senate bill which resulted from your testimony stated your Institute could spend up to an additional $6 million over then present levels of expenditures.

Did you take advantage of this opportunity to spend the additional $6 million on regeneration research?

If not fully, to what extent did you spend it?

Dr. TOWER. Senator Hatfield, I think there is a misunderstanding between the language and the budget.

If you look at the record, there was not a $6 million item appropriated. I can't give you the precise figures now, because I don't have them at my fingertips. But we have discussed this matter in correspondence before and, therefore, I would like to answer your question in a slightly different way, and to point out that between 1976 and 1979, the expenditures for research on trauma of the nervous system have approximately doubled.

In 1976, we spent $10.3 million on research for spinal cord injury and head injury, and that includes the amount for regeneration; and in 1979, we will spend $19 million for research on spinal cord and head injuries. So that amount of money has approximately doubled in that 4-year period.

I would think that it is perhaps more constructive to consider what we have been able to accomplish with the funds that have been provided for us, and I would point out that between 1977 and 1978, we have gone up almost $3 million in that expenditure for research on central regeneration.

So that even though the $6 million was not precisely appropriated, I think it appears in the results over that 4-year period of time.

Senator HATFIELD. I really would like to get clarification of that, because it happened to be my amendment that authorized you to increase that expenditure level.

I note that you went from $178 million to $212 million-plus in that budgetary year, and it would seem to me that with the intent that lay behind the amendment, and with the amount of the increase in your budget, there should not have been any confusion as to what you were actually authorized to do, and with the moneys that were increased to provide you with the capability of doing it.

Dr. TOWER. Senator, may I answer your concern this way: We are aware, first of all, of the importance of spinal cord injury and regeneration, and this is one of our highest priority items.

But in the increase in our budget from the $177 million to the $212 million figure, we were directed by the conferees to pay approved competing research grants through priority score to 250, and our records show that we will not be able to achieve that with the moneys that we have, due to the fact that we have been confronted with a considerable increase in research grant applications, and the quality of research which has provided those priority scores.

Second, we were also directed to deal with the recommendations of the Epilepsy and Huntington's Disease Commissions, and of the Diabetes Commission, When you put all of those together, there is just not enough money to go around to fully fund all of the initiatives. Therefore, we have tried to achieve a program balance, in which we have to put money into all of these areas to the best of our ability.

Senator HATFIELD. Would you pass by me once again your comments regarding the conferees instructions about 250?

Dr. TOWER. The conferees instructions were that we were to fund approved competing research grants through priority 250.

Senator HATFIELD. Here is the report, and both the minority and majority staff say they don't recall any such instructions by conferees.

Dr. TOWER. This is for the NIH generally, not for each Institute individually.

That came from the House. That did not come from the Senate. It came from the House.

Dr. FREDRICKSON. It is in the House report.

Senator HATFIELD. Then that is not the conferees. The conferees are equally divided. The Senate participates in that conference, and that is why none of our staff recalls such instructions from Senate conferees.

Of course, this is one of the frustrations that I'm sure that you feel at times, and which I feel now. That is, when an amendment is offered, and it is accepted and it specifies in fact instructions to an agency, and those instructions, then, are not carried out, whether it is due to conflicting instructions or otherwise, is not the issue. It is the frustration that follows by not having that kind of money expended in the areas, in the ways directed.

I don't like to get into such detail of earmarking. It is against my general philosophy, really. I suppose that comes out of my own days as 8 years as a Governor. I tend to react to such efforts by legislative bodies.

But I do feel that there are occasions when the kind of interest and support that is represented in the public generally has to somehow penetrate the agencies, and I am in no way being critical, Dr. Tower, of your record or efforts or commitment.

What I'm trying to underscore is the great desire that some of us have to undergird you, and to give you greater resources in which to pursue your objectives.

I think when there are such conflicting instructions, that there ought to be responsibility on your part to clarify, to know which ones should be followed, or which ones should be restated.

As I say, if I had not been an author of that Senate amendment on this very specific thing, I would not perhaps feel quite as strongly as I do.

We will have to perhaps go that specific routing again, to get the kind of level of research that we are striving to get in this particular area, and I would hope that there would be no confusion or conflict in such instructions, if it prevails, in the Senate and House conference, and it comes to you in the form of a completed budget.

But I want to assure you now, as a member of this subcommittee, that if there is such confusion, I would hope to inquire from you at any time for clarification, knowing definitely what the intent will be behind such specific instructions.

SPINAL CORD RESEARCH

The 1977 GAO study, entitled "Cost of Spinal Cord Injuries in the United States, and Progress of Spinal Cord Regeneration," mentioned the lack of central direction for spinal cord research in the Federal Government.

What steps are being taken to provide a more coordinated effort, if you feel that that statement is justified?

Senator TOWER. Senator, there are really two kinds of problems with spinal cord injuries. One is research, and the other is the acute and chronic management of those who have been injured, and these reponsibilities are divided, as you are aware.

The NINCDS has mounted the largest research effort in the world on the problem of spinal cord injury and the associated problems of regeneration in the central nervous system, and I think that we can, within the resources that have been available to us, point with considerable pride to what has been accomplished in this area.

The management and rehabilitation is the responsibility of the Veterans' Administration for those who qualify for that program, for the Rehabilitation Services Administration of HEW, and to some extent the emergency medical service program of the HSA part of the Public Health Service.

We do talk to each other. We have many common meetings together, and I think that within the resources that are totally available to the four agencies that I have mentioned, we have made many great strides in this area.

I would point particularly to the Veterans' Administration, in the area of management. They have a model system, for example in their hospital in Roxbury, Mass., under Dr. Rossier, who is probably one of the leading authorities in the world on the management of the chronic paraplegic patient. Through his efforts, the Veterans' Administration has seen fit to admit civilians, as well as veterans, to that facility, and I think that when they open their new building, which I believe will be ready sometime this year, this will provide an additional resource for what I may call research on the chronic management of the paraplegic.

In addition to that, we have been very aggressive in the development of neural prostheses aimed at dealing with the problems of the paralyzed patients, whether this be due to spinal cord injury or some other cause, such as stroke, or brain tumor.

We have at the moment a trial going on in experimental animals over the next 6 months at the University of California in San Francisco, where a new method of dealing with bladder control problems is being looked at. This is one of the serious complications of spinal cord injury, for example. This study is sufficiently promising, that we anticipate we will be able to adapt this to patients themselves within approximately 6 months.

There is a great deal of other research going on in how to interface the central nervous system with prosthetic devices, and we expect these to pay off as we go along. We already have some of these, but there are many more in the works.

In addition to that, we have just taken off now, after a feasibility stage study on a joint effort by our five acute spinal cord injury

research centers and two other centers which have joined us, a seven-center collaborative prospective randomized trial of high doses of steroid therapy in the acutely injured spinal cord patient.

On the basis of preliminary data, there is indication that aggressive treatment of the acutely injured patient, whether it is spinal cord injury or head injury, will achieve a very significant reduction in mortality, as well as a much better outcome.

This trial is now just getting underway, and I think within a year or so, we will be able to see the results of that.

Senator HATFIELD. That is the PETT project. You referred to the PETT project.

Dr. TOWER. No, sir, that will take longer. But these steroids in acutely spinal cord injured patients, I think, will be a very significant advance in our understanding of how to manage the acutely injured patient.

Senator HATFIELD. I noted that you said that this progress has been made within the confines or within the restrictions of the resources.

I just want to indicate to you, Dr. Tower, that hoping that you will put the same kind of priority that you put on your PETT project, as indicated in the testimony yesterday, where you said to this committee, you were committed to this kind of project; that it would be pursued regardless of budgetary restraints.

I would like to have you know that I'm willing to give you any kind of support to reduce the constraints that you may feel or have at this time on accelerating or escalating this particular spinal cord program, at least as one member of this committee.

I can't speak for the full subcommittee, but I do want you to know that you have a supporter, a full and complete and unreserved supporter for this Institute. We have to acquire support from our colleagues, that any one of us has to have a strong commitment.

Dr. TOWER. I appreciate that, Senator.

HIGH PRIORITY PROGRAMS

Could I make one further comment, to put into perspective these programs.

From a public health standpoint, the three most important programs that we have, in terms of the numbers of patients involved and the cost to society, are stroke, which is No. 1, because of the very high mortality in the large number of afflicted patients; epilepsy, No. 2, and No. 3, trauma to the nervous system, which is head injury and spinal cord injury.

And I put them together because many of the research problems are common, and in many of the injuries they involve both head and cord areas.

Our expenditure for these three areas are approximately the same: stroke, in 1979, $17.4 million for research; epilepsy, $18.9 million for research; and trauma, both head and spinal cord injury, $19 million for research.

I believe that puts into perspective our efforts.

We try to deal with the many problems that we are confronted with. Our difficulties have to do with the fact that there are many

unknowns in all of these areas, and many of these problems are shared by the three areas I have cited, in terms of mechanism, dysfunction, and so on. So that a great deal of the research work is basic research, which must range across the whole area. When you look at trauma of the nervous system, no matter where it occurs, you deal with problems of ischemia, the lack of sufficient blood supply to the nerve cells, plus the development of edema.

So the research on these two problems becomes highly important. When you look at regeneration, and I was thinking about it as you were talking about where you put your priorities, in times of austerity, it becomes very difficult, if you take central regeneration as a particular example.

Because, first of all, the nerve cell must grow back, and we have problems of understanding the basic physiology, biology of the nerve cells in that regard: such research problems as axonal transport, which deals with how the nutrients and the necessary materials are delivered at the growing end of the nerve type.

Second, you have symbiosis of the supporting cells, and particularly the development of the insulation around that nerve fiber as it grows down. This ranges across all sorts of problems, even gets you into multiple sclerosis, an understanding that problem and going on to the problem of the growth.

These two basically deal with the first question in regeneration. That is either regrowth by the nerve cell or substitution by another nerve cell, in the area where the function has been lost.

Then you have the problem of making the right connection. There is no use to grow a nerve fiber if it can't connect with the right muscle or right gland.

There you get into the whole basic research problem of transmitters, of trophic functions, nerve growth factor, and the like.

We know in experimental animals that sometimes connections can be made in the wrong way, and you get a useless functional result which does not allow the animal to walk, for example, even though the innervation has been completely restored.

So we have these basic kinds of research problems which range across the whole area. When you deal with how to determine priorities at a basic research level, it becomes extraordinarily difficult, because no one of us at any single time is wise enough to know which horse is the only one to bet on.

So we have to bet on a lot of horses simultaneously.

Senator HATFIELD. Thank you very much.

I'm glad I asked that question.

I said I wanted to be educated and tutored, and I appreciate that very much.

Were you in the classroom at one time, sir?

Dr. TOWER. No, sir.

Senator HATFIELD. You would make an excellent professor, I assure you. Having been in that classroom, I recognize a master teacher.

I have some other questions, Dr. Tower, relating to the same subject, which I would like to submit to you in writing for the record.

Dr. TOWER. Yes, sir.

QUESTIONS SUBMITTED FOR RESPONSE

[The following questions were not asked at the hearing, but were submitted to the Department for response subsequent to the hearing:]

SPINAL CORD CENTERS

Question: Would it be possible for NINCDS to make available a listing of spinal cord treatment centers and other related information for immediate dissemination to physicians and families of victims of acute injuries?

Answer: At the present time there is no national or regional program of clinical care centers for the treatment of persons with acute injury of the spinal cord. Clinical care is provided to the acutely injured in a large variety of local facilities ranging from the smallest local hospitals to major university centers. For the rehabilitative care of the long-term consequences of spinal injury, the Rehabilitation Services Administration is evaluating regional patterns of rehabilitative care.

Thus, it is not possible at this time to develop a list of spinal cord treatment centers or facilities since there is neither a non-government nor government registry of such centers. The establishment of a registry would require the establishment of national standards for the care of the spinal injured and the evaluation of all units proposing to be designated as centers.

However, in Fiscal Year 1979, the NINCDS successfully completed a feasibility study for the establishment of regional comprehensive centers for central nervous sytem--CNS--trauma, including acute spinal cord injury and acute head injury. The NINCDS has proposed launching this comprehensive CNS trauma center program in FY 1980 with the objectives of demonstrating nationally the effectiveness of coordinating clinical services in regional centers of excellence and for the evaluation of available methods of early diagnosis and therapy. The plans for these comprehensive CNS trauma centers were developed in consultation with the NINCDS supported Clinical Research Centers in areas of acute spinal cord injury and acute head injury in which new and improved methods of early diagnosis and therapy are being developed, and with the clinical care programs of the Emergency Medical Services and Veterans Administration. In this way, a national network of regional centers would be established which are dedicated to the problems of the care of victims of spinal cord and head injury.

DIMETHYL SULFOXIDE--DMSO

Question: There is increasing evidence that the drug, DMSO, developed by Dr. Stanley Jacob of the University of Oregon, may have been beneficial in restoring some voluntary muscle functions to chronic paraplegic victims. Does NINCDS plan to investigate significantly the use of DMSO in this regard?

Answer: NINCDS has in the past and is presently sponsoring research on the use of DMSO in acute central nervous system trauma. This has been laboratory research and has been done by investigators at The University of Chicago, New York University, Ohio State University, and the University of Texas in San Antonio. In addition the clinical use of DMSO, in patients with brain and spinal cord trauma, is being studied at The University of Chicago and The University of Miami. Only small numbers of patients have

so far received DMSO. Attention has been given to treatment of the acutely central nervous system-injured patient because it has been the experience of most investigators that if neurologic deterioration is to be prevented or reversed by treatment, that treatment should begin as soon as possible after injury.

In view of reports of improvement in three patients with chronic spinal cord damage at the University of Oregon, collaborators at the University of Miami have expressed interest in setting up a research protocol for the study of the effects of DMSO on chronically paraplegic laboratory animals and are preparing an application for submission to NIH.

LOU GEHRIG'S DISEASE

Question: Last year, Dr. Tower, The Committee expressed concern over lack of emphasis or funding for amyotrophic lateral sclerosis or ALS (Lou Gehrig's Disease). What have you done in the area in Fiscal Year 1979?

Answer: In Fiscal Year 1979, the Institute has funded one of the two new approved applications submitted to date for research specifically related to ALS. The priority score of the second was not sufficiently high to warrant funding. We are continuing funding of a clinical program project in ALS at St. Vincent's Hospital and Medical Center in New York City; a research project at Montefiore Hospital in New York, as well as one at Johns Hopkins University. Continuation funding is also being provided for a clinical program project which deals with the pathogenesis of both ALS and Multiple Sclerosis at the Scripps Clinic and Research Foundation in La Jolla, California. Support is also being continued for a project investigating the viral etiology of ALS at the University of Southern California.

The NINCDS Intramural Research Program conducted several therapeutic trials based on the possibility that ALS may be a chronic viral infection. Although in one study, poly-ICLC failed to benefit ALS patients, an individual with a possibly related disorder did improve. In another clinical trial, phtalazinol, succeeded in correcting one of the biochemical abnormalities found in spinal fluid of ALS patients, but did not modify the clinical course.

Other in-house studies included one which sought a genetic marker which might indicate an individual's susceptibility to ALS; a continuing investigation of the special metabolic characteristics of spinal nerve cells preferentially affected in ALS; and research on an inherited motor neuron degeneration in mice as a possible animal model for ALS. Investigators at the Guam Research Center have during the past year, tested the hypothesis that host resistance factors may be abnormal in Guamanians with ALS.

Question: And what are your plans in 1980 with your budget request as it is?

Answer: In 1980, we will continue support of these projects and perhaps be able to fund one or two relatively small new research grant awards. The Institute's intramural research on Guam will

continue to focus on the role that diminished cellular immunity might play in ALS and collaborative studies will be initiated with Japanese scientists on the possible participation of certain metals--for example, aluminum, calcium, and magnesium--in predisposing individuals to ALS. Studies to identify a possible viral agent in Guamanian ALS brains are also to be expanded. On-campus research in FY 1980 will included additional therapeutic trials including adenine arabinoside, a new antiviral agent.

Question: What is the current status of funded grants and contracts as well as your intramural programs in Fiscal 1979 and 1980 versus what you were doing in, say, 1977 and 1978?

Answer: The estimated Fiscal 1980 research support is $2,760,000, the same level as 1979 compared to 1977 of $1,601,000 and 1978 of $1,730,000.

PRESIDENT'S WAGE AND PRICE GUIDELINES

Question: Dr. Tower, I would like to ask you this question and then maybe Dr. Fredrickson and Mr. Schwartz may also want to comment.

In terms of increases provided for salaries in all of your grants and contracts, are you sticking to the President's wage and price guidelines?

Answer: The NIH depends on the salary guidelines of its grantee institutions in making awards. The university community is subject to the President's guidelines and is attempting to meet them. We will do whatever is appropriate to help them.

Question: What impact will it have on your budget next year?

Answer: Upward adjustments of salaries within the President's wage and price guidelines will result in a modest increment in the personnel category of most research grants for next year. This effect has already been taken into consideration in preparing the FY 1980 budget request.

Division of Research Resources

STATEMENT OF DR. THOMAS G. BOWERY, DIRECTOR

ACCOMPANIED BY:

DR. DONALD S. FREDERICKSON, DIRECTOR, NIH
RICHARD L. SHAFER, EXECUTIVE OFFICER, DRR
H. RICHARD MILLER, ASSISTANT DIRECTOR FOR BUDGET, DFM, NIH
KENNETH S. LEVINE, DEPUTY ASSISTANT SECRETARY FOR LEGISLATION
WILFORD J. FORBUSH, DEPUTY ASSISTANT SECRETARY, BUDGET

PREPARED STATEMENT

Senator Hatfield. Next we will turn to Dr. Bowery, the Director of the Division of Research Resources.

Because of time constraints, let me place your comments in the record, if I may, Dr. Bowery, and go to the first question.

[The statement follows:]

STATEMENT OF DR. THOMAS G. BOWERY

Mr. Chairman and Members of the Committee:

Once again it is my pleasure to speak before you on behalf of the Division of Research Resources. It is the Division's mission to develop and support those research resources which provide the necessary instruments, technologies, animals, and special environments in which, and with which, the NIH mission is accomplished in colleges, universities, medical schools and other research institutions throughout the Nation. Our resources, as a group, are bound by neither a disciplinary focus nor a categorical disease focus; consequently, they are used by investigators conducting research in all fields of NIH endeavor -- basic and applied investigations in biomedical and behavioral research.

To develop and support these research resources, which are the undergirding foundation for bioscientists regardless of discipline or field of interest, we focus our efforts on two fronts. The first of these has to do with the actual resource itself. Through extensive collaboration and interaction with our grant and contract-supported principal investigators, we assure that the resources themselves are continually undergoing development and improvement to provide state-of-the-art resources; that is, the best possible instrument, animal, or environment. Secondly, through more widespread collaboration, we assure that the resources are available to, and used by, many investigators to accomplish their particular research goals.

Clinical Research

The Division provides resources for clinical research through the General Clinical Research Centers Program. These Centers, which began as inpatient research units in teaching hospitals across the Nation, have evolved over the years to the point where many Centers now study ambulatory patients as well. These outpatients provide a unique population for research at a significantly lower cost than do hospitalized patients; and, while not all kinds of clinical research can be accomplished using ambulatory patients, that which can is now being supported at high quality/low-cost levels. Another development is the Clinical Associate Physician Program which operates within the Centers. It provides a research milieu wherein a qualified physician can develop research capabilities in clinical investigation.

An additional development in the Clinical Research area is the CLINFO Data Management System which the Division developed, and is now evaluating. CLINFO Systems will be placed competitively next year in five to ten General Clinical Research Centers where they will significantly increase the research physicians' data management capabilities and, at the same time, greatly extend the investigators' ability to rapidly analyze and interpret the information resulting from their clinical research. It is anticipated that this System will also be available for purchase by clinical research units other than the Centers in the near future.

Biotechnology Research

The Division's Biotechnology Research Program brings together emerging and available instrumentation technologies and biomedical research needs. What began as an effort to apply the power of computers to research data processing several years ago has evolved into an approach to develop and provide technological tools to biomedical and behavioral investigators throughout the Nation. The capabilities of very specialized research computer facilities are now being applied to major problems of understanding the process of disease diagnosis. Investigators at the University of Pittsburgh have developed a series of computer programs called "Internist" which mimics with remarkable fidelity the capability of physicians to diagnose many diseases.

A different application of computer power, the PROPHET Computer System is the heart of our Chemical/Biological Information Handling resource. This System allows pharmacologists and toxicologists to investigate the effects of drugs on human systems using computer-based models.

The structure and function of the biochemical constituents of living cells represents the second facet. These are best undersgood using very sophisticated techniques such as mass spectroscopy, electron microscopy, electron microprobe analysis, and others. In 1978, a new resource was added to this portfolio, an X-ray crystallography resource which will allow investigators to build upon

existing knowledge about the structure of proteins and understand complicated protein molecules and, consequently, more about how proteins function in biological systems.

Resources for bioengineering provide a capability for developing engineered devices for research. One such resource has produced a flat-surface pressure transducer which can be used to measure the blood pressure of patients in hypertension studies. It is significantly easier to use and no more expensive than the blood pressure cuff which is currently in widespread use.

Cellular and biochemical materials is a fourth area of technology application. An example is the Nation's only stable isotope resource at Los Alamos which is funded jointly with the Department of Energy. Molecules such as heavy carbon, oxygen and nitrogen are used in metabolic studies with humans and carry with them none of the radiation risks associated with using radioactive isotopes. A primary objective is to accelerate the development of stable isotope tracers in biomedical and environmental studies. For example, a large quantity of carbon-labeled fluids is used in a breath test that detects fat malabsorption.

Laboratory Animal Sciences and Primate Research

One of the most widely used research resources in biomedical investigation is the research animal. It is through the Laboratory Animal Sciences and Primate Research Program that the Division helps to assure that the research conducted using research animals is as effective as possible. To that end, we continue to support the development of animal models of human disease. We also support a number of special colonies of unusual, unique, and important research animals. A very important portion of our Animal Resources Program is the support of 15 animal diagnostic laboratories. These laboratories serve to identify and reverse the effects of diseases which occur within colonies of research animals.

The seven Primate Research Centers which the Division supports offer a nationwide group of shared resources using nonhuman primates. This program of Centers, when taken as a whole, provides focused research environments using monkeys, great apes, and other nonhuman primates for research on environmental health problems, behavorial problems, and the many other disease areas within the NIH mission. Research on ways of producing domestic nonhuman primates for research, as well as the actual production, also fall within the purview of the Laboratory Animal Sciences and Primate Research Program of this Division. By 1980, it is anticipated that the Primate Centers will be producing 1,500 animals which is about 61% of the nonhuman primates required for their own research needs, and other sources funded by the Division will be producing 2,000 animals which is about 55% of the Division's share of the national breeding goal for the use of investigators other than those using the Primate Centers. A special report requested by the Congress has been provided to the Subcommittee detailing the current needs for primates for research and the Division's efforts in meeting those needs.

We also support resources which provide information to users of primates about the availability of primates that are being, or that have been, used in other studies since, in many cases, these animals are not sacrificed but often can be used again and again in other studies.

A small but effective component of this Program provides National Research Service Awards for training in Laboratory Animal Medicine. Trainees are prepared for careers encompassing teaching and research as well as service to investigators through management of central animal resources. There are currently 11 active training programs with a total of 33 funded trainee positions. The 10-12 graduates per year have been rapidly assimilated into the field, and many institutions are still experiencing difficulty in recruiting well qualified laboratory animal veterinarians.

Biomedical Research Support

The Biomedical Research Support Grant continues to be an extremely important research resource which is invaluable to the recipients of these funds. The grant is a unique NIH mechanism that provides flexible funds to 464 institutions for their self-determined use in a number of specific ways for the support of ongoing biomedical and behavioral research. Grantees are encouraged to use these funds for pilot research projects and for initiating young investigators into full-fledged research activities. For example, at the University of California School of Dentistry, Los Angeles, BRSG funds supported pilot studies which led to the establishment of a new model system for the development of bone in tissue culture. Also, these funds help institutions to stabilize their research programs and to

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provide more appropriate and cost/efficient central research services, such as support for shared instrumentation, repairs on instruments, and centralized animal facilities.

A subprogram of Biomedical Research Support is the Biomedical Research Development Program. This program provides support on a competitive basis to assist new, small, or developing institutions who have demonstrated a need for improving their research environment to enable them to produce better trained health professionals. Initiated in FY 1977, at the request of the Congress, the current 23 grantee recipients include schools of medicine, dentistry, pharmacy, veterinary medicine, and other health professional and research institutions.

Minority Biomedical Support

The Division's Minority Biomedical Support Program assists minority institutions, faculty, students, and investigators to become more directly involved in the mainstream of biomedical research. Our grants to recipient institutions supported some 500 research projects in 1978 which were conducted by 2,000 faculty and students at predominantly minority institutions. Last year, 83 of those projects were partially supported with funds provided by other NIH Institutes. One measure of success of the Program is the 400 research papers presented at the 1978 Annual Minority Biomedical Support Symposium which was held in Atlanta, Georgia. The important two-fold contribution of this Program is that important scientific research is being accomplished, and it is being done by minority investigators who, prior to the inception of this Program, had little chance of becoming involved in this research.

The Division's work in both developing and supporting the several kinds of research resources continues. This year, Fiscal 1980, our budget request for all these programs is $154,199,000. I will be pleased to answer any questions you have about this request.

BIOMEDICAL RESEARCH SUPPORT GRANT PROGRAM

Senator HATFIELD. The Biomedical Research Grant Program is one which the committee has been very supportive of in the past.

Would you briefly describe this program as you see it at this time, and how does it fit within your priorities?

Also, what is the budget request for 1980, as compared to last year?

Dr. BOWERY. The budget request for last year for this program was $44,914,000. The budget request for 1980 is $44,840,000, a slight decrease of $74,000.

This program continues to be one of high priority for the division. It makes awards to some 450 institutions around the country.

The state of Oregon is receiving five institutional awards for approximately $533,000.

The continued emphasis on the program is for funds that would be utilized in a cost-effective manner.

The emphases are on short-term, nonrecurring activities. These basically fall in the areas of supporting pilot projects, young investigators, and helping to establish and maintain shared resources within an institution where more than one investigator or group can use the facilities. These funds are also used for unanticipated emergencies that arise in any kind of dynamic research situation in an institution.

The range of the awards are from a low of around $14,000, to a high of around $200,000.

This is a formula allocation program, with the average award being approximately $86,000.

The fundamental difference between this and the specific categorical research programs is that once the money is allocated to an institution, essentially the decision as to how it is to be spent is made by the chief scientific officer of that institution, supported by the local advisory committee.

We feel this is cost-effective in reducing the overhead cost of having the institution file a number of grant applications for supplementation of specific research projects.

It also reduces overhead costs to the NIH Institutes by reducing the number of applications that would be received if we didn't have this particular mechanism.

The Congress originally authorized this program to use up to 15 percent of the money made available to NIH for its extramural research grants activities.

It never has reached that level.

It is now running around 2½ percent, much less than the authorized level.

Senator HATFIELD. Thank you, Dr. Bowery.

OVERCOMING THE SHORTAGE OF PRIMATES

You mentioned the Oregon facility. Of course, it is one of a number.

As I understand, there has been a ban on the export of the India monkey, the rhesus monkey, which is the primary animal used to do research, at least in the Oregon center.

There is, I understand, an almost critical shortage of the primate supply.

How do you account for this loss?

Dr. BOWERY. We are taking a number of approaches to overcome the shortage.

One is the development of a national primate plan. The National Institutes of Health, represented by my Division and the Division of Research Services, under the leadership of Dr. Held, is working with a number of other agencies to establish a primate plan. The plan essentially says the Nation should give priority to the development of domestic breeding capacity, so as to be able to serve the needs where primates are necessary, such as the production of vaccines.

Second, the conditions and priority for the use of primates for research purposes is set forth. A draft copy of the plan was made available to this committee last year. It is currently undergoing final review before release. Within the Division's programs, we have established at the University of Washington primate research center in Seattle, a neighbor of the very excellent center in Oregon, a primate information clearinghouse. Primates which have been used for one research project can be made available to another institution so that there is multiple use of the animals. Also, in the case where, after careful research considerations, the animal has to be sacrificed, parts of that animal are then rerouted to other investigators for further research purposes.

We are using everything from those primates which must be sacrificed for research purposes.

Dr. FREDRICKSON. Senator Hatfield, if I might say this——

Senator HATFIELD. Very colorful description.

Dr. FREDRICKSON. I think the primate plan is much too long, to be submitted for the record.If you would like a brief analysis of the rhesus situation, we can provide that for you.

We have taken steps to increase our breeding capacity, although we will never have enough for biomedical research. In 1980 I would guess the requirements remain the same, about 14,000 rhesus in this country; and we will be able to provide about 2,000 for the most critical needs. The single most critical need is the checking of polio vaccine at the present time.

We would be glad to provide you with that information.

PRIMATE RESEARCH CENTERS

Senator HATFIELD. This primate center system was established, what, about 15 years ago?

Dr. BOWERY. The first center was at the University of Oregon in 1962, and the publication that I am showing you now describes each of the centers, and it also describes the activities at Oregon.

The current budget level for the primate research centers is at about $15.2 million, and in the 1980 budget will remain the same. The inflationary pressures on the research carried out in these centers is currently somewhere between 6 and 8 percent.

Senator HATFIELD. I would have thought that in this period of time that we could have built up some colonies, either outside or within the primate centers, to develop a little more local and domestic supply?

Dr. BOWERY. Yes. We have currently a combination of 11 grants and contracts that are developing some capacity within the United States to have a domestic supply to be made available.

These are grants and contracts outside of the centers themselves. Within the centers they are also striving to attain self-sufficiency, and they are at approximately a 60 percent level of their own internal needs.

We can put into the record the number, location and amount of funds for these primate breeding activities.

Senator HATFIELD. Population activity, and so forth.

Thank you very much, Dr. Bowery.

Dr. BOWERY. Yes, we will include information on the types and number of animals involved. Thank you.

[The information follows:]

PRIMATE BREEDING PROGRAM

A number of Federal agencies and other organizations are supporting primate breeding programs to supply animals for their own programs. The Division of Research Resources (DRR) of the National Institutes of Health (NIH) supports nonhuman primate breeding programs to supply animals for use on NIH grants and contracts. The DRR program itself has two components. They are the Regional Primate Research Centers breeding programs which produce animals for the Centers' own needs and a group of resource grants and contracts which produce nonhuman primates for use on other NIH grants and contracts.

The Primate Research Centers have a long range goal of becoming self-sufficient with respect to nonhuman primates required for their own research programs. They currently have achieved about 60% of this goal. Table I details the status of the Primate Centers breeding programs.

In addition to the Primate Research Centers breeding program, the DRR supports 11 grants and contracts specifically for the purpose of providing a basic supply of primates for NIH extramural research. Domestic breeding of all primates needed for NIH extramural research is not required in the immediate future as some animals can still be obtained from wild-caught sources. In order to provide a basic supply of these animals, we believe that at least 40% of the total needed should be producted domestically.

The five grants currently supported tend to focus on research and development of primate breeding techniques, with production a secondary objective. The six contracts focus more on production and less on research and development. The contracts for rhesus monkey production were delayed in achieving their production goals because of difficulties in obtaining breeding stock, but by 1980 contract production goals for rhesus as well as cynomolgus monkeys seem likely to be substantially achieved. The contracts for production of squirrel monkeys will not meet their production goals, and it is obvious more research on domestic breeding of this species is required. Table II details the status of DRR's breeding programs for NIH extramural research other than the Primate Research Centers.

We have prepared an overall status report on primate supply which describes the national picture as well as DRR's program. A copy of that report is attached for your reference. It indicates the national requirements for rhesus monkeys is about 14,000 annually and that by 1980 domestic production will be about 5,000 of which we will be able to provide about 2,000.

TABLE I

STATUS OF PRIMATE RESEARCH CENTERS BREEDING PROGRAMS

	Rhesus Monkeys	Cynomolgus Monkeys	Squirrel Monkeys	Other Primates	Total
Annual Requirement	1,100	150	225	1,025	2,500
Production Goal	1,100	150	225	1,025	2,500
Fiscal Year 1978					
Production	770	50	100	530	1,450
Percentage of Goal	70	33	44	52	58
Budget	.....not broken down by species.....				$1,477,000
Fiscal Year 1979					
Projected production	785	55	100	594	1,534
Percentage of Goal	71	37	44	58	61
Budget	.....not broken down by species.....				$1,565,000
Fiscal Year 1980					
Projected production	800	60	100	640	1,600
Percentage of Goal	73	40	44	62	64
Budget	.....not broken down by species.....				$1,660,000

TABLE II

STATUS OF DRR PRIMATE BREEDING PROGRAMS FOR NIH EXTRAMURAL RESEARCH OTHER THAN PRIMATE RESEARCH CENTERS

	Develop. of Tamarin & Marmoset Production (3 grnts)	Develop. of Baboon Product. (1 grnt)	Develop. of Owl Monkey Product. (1 grnt)	Rhesus Monkey Product.1/ (3 cntrcts)	Squirrel Monkey Product. (2 cntrcts)	Cynomolgus Monkey Product. (1 cntrct)	Other Primate Product.	TOTAL
Annual Requirement	645	400	590	2,400	1,195	2,250	1,300	8,780
Production Goal	345	-0-	15	1,700	400	1,200	95	3,755
Currently Funded Contract Goals	-0-	-0-	-0-	1,700	400	150	-0-	2,250
Fiscal Year 1978								
Production	71	-0-	-0-	790	60	50	-0-	971
Percentage of Goal	21	-0-	-0-	46	15	0.4	-0-	26
Budget	$273,000	$410,000	$84,000	$576,620	$173,788	$50,000	-0-	$1,567,408
Fiscal Year 1979								
Projected Production	165	50	5	1,080	90	100	-0-	1,490
Percentage of Goal	48	-0-	33	60	23	0.8	-0-	40
Budget	$182,000	$119,000	$62,000	$601,718	$190,946	$77,081	-0-	$1,232,745
Fiscal Year 1980								
Projected Production	187	170	10	1,440	115	150	-0-	2,072
Percentage of Goal	54	-0-	67	85	29	1.2	-0-	55
Budget	$182,000	$134,000	$70,000	$623,246	$195,000	$85,000	-0-	$1,289,246

1/ Includes production from one commercial colony that NIH has first priority to purchase from.

STATUS REPORT ON NONHUMAN PRIMATE SUPPLY

Progress is being made to assure a supply of nonhuman primates essential for biomedical research in the face of drastically curtailed importations of wild-caught animals. The overall Federal effort in primate supply is being coordinated through an Interagency Primate Steering Committee (IPSC). This Committee functions to assemble overall information on the National needs for primates, assesses the foreign and domestic supply, recommends general policies for the use nonhuman primates, serves as the principal contact point for international programs relating to primate supply, and plans and coordinates a national program of domestic primate production. As part of its responsibilities, the IPSC has nearly completed a National Primate Plan. A copy of the plan will be provided when it is released. The plan will analyze the supply situation for each primate species of biomedical importance and recommend actions which should be taken to assure a continuing supply of nonhuman primates for biomedical research use. The plan will recommend three major categories of action; i.e., (1) domestic primate breeding, (2) conservation of primate use, and (3) stabilization of foreign sources of supply. Within this overall context, each Department or Agency of the Federal government or private organization has responsibility to implement those actions necessary to assure a supply of primates for activities for which it is responsible.

Domestic Primate Breeding

A number of agencies and organizations are supporting domestic primate breeding to supply animals for their programs. The Division of Research Resources (DRR) of the National Institutes of Health (NIH) is responsible for implementing primate breeding programs to produce animals for use on NIH-supported grants and contracts. The DRR program itself has two components for primate breeding. They are as follows: (1) the Regional Primate Research Centers program, which is breeding animals for use in the research programs of the Primate Centers themselves and (2) a group of resource grants and contracts which produce nonhuman primates for use in other NIH grant or contract supported activities requiring primates.

The seven Regional Primate Research Centers were established in the early 1960's to provide multidisciplinary research resources for investigators wishing to conduct medical research using primates. Today, they accommodate about 125 core staff scientists and 600 affiliated investigators working on 250 research projects. The Primate Research Centers have a long-range goal of becoming self-sufficient with respect to primates required for their own research programs. They intend to accomplish this goal principally through domestic production within the Centers. The Primate Centers have made good progress with their breeding programs. In FY 1978 they produced about 1,450 infants and fetuses, which represents about 60% of their annual requirements. Table I sets forth the requirements for animals by species for the seven Regional Primate Research Centers,

actual production figures for FY 1978, and projected production for FY 1980 and 1982. The latter projections are made on the basis of current funding levels.

Outside of the Primate Research Centers, there are over 1,000 NIH grant or contract-supported research projects which require primates. The DRR supports 11 grants and contracts specifically for the purpose of providing a basic supply of primates for these NIH extramural activities. Five grants tend to focus on research and development of primate breeding techniques, with production a secondary objective. Six contracts focus more on production and less on research and development. Table II sets forth the estimated requirements, the breeding goal based on an appropriate portion of the overall National Primate Plan goal, the FY 1978 actual production, and FY 1980 and 1982 projected production for NIH extramural research.

Other agencies and organizations are also supporting domestic primate breeding to supply animals for their programs. Significant production efforts are being supported by the Food and Drug Administration to produce rhesus monkeys used to test the polio vaccine; the Division of Research Services, NIH, to produce primates used in the NIH intramural research programs; and Lederle Laboratories to produce rhesus monkeys for the manufacturer's testing of polio vaccine. Lesser numbers of animals are being produced by some of the NIH Institutes, the Center for Disease Control, and other research organizations to meet their own specialized needs for nonhuman primates. Table III sets forth the estimated primate requirements, the relevant portion of the National Primate Plan breeding goal, and the production programs of these agencies and organizations.

Table IV is a summary of Tables I, II, and III and provides a comprehensive picture of domestic primate breeding. In cases where there is a difference between the estimated requirements and the National Primate Plan breeding goal; it is assumed the difference will be supplied from wild-caught sources, re-use of animals, or will be made up by use of other species.

Conservation of Primate Use

The IPSC has set forth criteria which are designed to assure effective use of these animals. All Federal agencies represented on the IPSC have accepted these criteria for primate use, which are as follows:

- That the research proposed can be done best with primates; i.e., that no other known system or other kind of animals could produce comparable results.

- That the species of primate proposed is the most appropriate and that some other more plentiful species would not be adequate.

- That the number of primates proposed is the minimum that will produce acceptable scientific results.

- That the primates will not be sacrificed during or at the end of the study except in those cases requiring termination as part of the investigation.

- That, if sacrifice is deemed necessary, positive action will be taken to share body material when feasible.

The DRR is supporting a Primate Supply Information Clearinghouse. This Clearinghouse is operated by the Washington Regional Primate Research Center and serves to match investigators who need primate animals or tissues with other investigators who have surpluses of animals or can supply primate tissues and body fluids. We estimate that this service is "saving" over 2,000 primates per year.

The activities to conserve primate use have been very effective in reducing the number of primates used in biomedical research. The use of primates is now only about 60 percent of what it was five years ago.

Stabilization of Foreign Supply

In spite of domestic primate breeding and conservation of use, the United States is still dependent on foreign sources for a significant portion of the primates required. Because of continued habitat destruction and concern for conservation of species, wild-caught animals should not be considered as a reliable long-term source. The Government of India banned the export of all nonhuman primates, including the widely-used rhesus monkey, effective April 1, 1978. Rhesus monkeys have recently been imported from Bangladesh, but field biologists have estimated that the Bangladesh population of rhesus monkeys cannot support the recent levels of exportation over the long term. Chimpanzees are critically needed for research on and testing of hepatitis vaccine, but are practically impossible to import into the country because they are designated as being in danger of extinction by the International Convention on the Trade of Endangered Species. There is no immediate threat to the supply of wild-caught baboons, African green monkeys or cynomolgus monkeys, but their long-term availability from the wild cannot be assumed.

Certain steps have been taken to stabilize the supply of primates from foreign countries. The Interagency Primate Steering Committee, working with funds made available by the Division of Research Services, NIH, has established a cooperative primatology program with the Pan American Health Organization. This program provides for breeding of indigenous primate species in selected South American countries as well as carefully controlled and limited cropping of wild animals for export to the United States. Bilateral programs of technical cooperation in conservation and management of wild primate populations are also under development in a number of countries; i.e., Malaysia, India, and Argentina. The DRR's Primate Research Centers have also established modest field stations in Indonesia and Kenya. These stations provide a base for studies in those countries and are a source of animals for the Primate Research Centers program.

Conclusions

Overall progress in overcoming primate shortages has been good. To date, there have been few disruptions of important biomedical research projects because primates were not available. Substantial numbers of primates are being bred in this country. Efforts to conserve the use of primates have been more effective than was originally projected. However, some problems do exist. The breeding of some species of primates, particularly those from South American countries, has proven to be more difficult than originally expected. Other species, such as the rhesus monkey, are breeding well; but the domestic production programs are very costly. We continue to be partially dependent on imported or wild-caught animals, and this source of animals must be regarded as tenuous. Implementation of many of the recommendations of the National Primate Plan will require additional funding. The plan estimates that $14.2 million would be required over a two-year period to implement its recommendations. Thereafter, $5.5 million per year would be required to maintain the program.

TABLE I

Primate Supply Requirements and Breeding Programs
for the Primate Research Centers

Species	Annual Requirement	Breeding Goal	FY 1978 Actual Production	FY 1980 Projected Production	FY 1982 Projected Production
Rhesus monkeys	1,100	1,100	770	800	800
Cynomolgus monkeys	150	150	50	60	65
Other Macaques	500	500	400	420	450
Tamarins*	200	200	15	20	30
Common marmoset	5	5	3	5	5
Owl monkey	70	70	16	20	30
Chimpanzee	15	15	8	9	10
Gibbon	-0-	-0-	-0-	-0-	-0-
Baboon	100	100	17	20	30
African green monkey	20	20	7	10	10
Squirrel monkey	225	225	100	100	100
Other	115	115	64	70	70
TOTALS	2,500	2,500	1,450	1,534	1,600

*Saguinus species

TABLE II

Primate Supply Requirements & Division of Research Resources Breeding Programs for NIH Extramural Research Other Than Primate Research Centers

Species	Annual Requirement	Share of Nat'l Plan Breeding Goal	FY 1978 Actual Production	FY 1980 Projected Production	FY 1982 Projected Production
Rhesus monkeys	2,400	1,700	790	1,440	1,700
Cynomolgus monkeys	2,250	1,200	50	150	150
Other Macaques	100	- -	-0-	-0-	-0-
Tamarins*	500	200	46	87	97
Common marmoset	145	145	25	100	100
Owl monkey	590	15	-0-	10	12
Chimpanzee	85	85	-0-	-0-	-0-
Gibbon	50	10	-0-	-0-	-0-
Baboon	400	- -	-0-	170	160
African green monkey	580	- -	-0-	-0-	-0-
Squirrel monkey	1,195	400	60	115	170
Other	485	- -	-0-	-0-	-0-
TOTALS	8,780	3,755	971	2,072	2,389

*Saguinus species

TABLE III

Primate Supply Requirements and Breeding Programs for NIH Intramural Research, Other Federal Agencies, and Other Biomedical Organizations

Species	Annual Requirement	Share of Nat'l Plan Breeding Goal	FY 1978 Estimated Production	FY 1980 Projected Production	FY 1982 Projected Production
Rhesus monkeys	10,515	6,200	1,500	3,000	5,500
Cynomolgus monkeys	3,605	1,650	40	50	65
Other Macaques	395	20	20	20	20
Tamarins*	1,490	410	250	300	333
Common marmoset	20	20	10	15	15
Owl monkey	805	65	10	30	63
Chimpanzee	80	80	40	60	80
Gibbon	50	10	5	5	10
Baboon	782	-0-	-0-	-0-	-0-
African green monkey	1,475	180	50	100	190
Squirrel monkey	3,025	175	100	150	175
Other	390	345	300	330	345
TOTALS	22,632	9,155	2,325	4,060	6,796

*Saguinus species

TABLE IV

Primate Supply Requirements and Breeding Programs
National Summary

Species	Annual Requirement	Nat'l Plan Breeding Goal	FY 1978 Estimated Production	FY 1980 Projected Production	FY 1982 Projected Production
Rhesus monkeys	14,015	9,000	3,060	5,240	8,000
Cynomolgus monkeys	6,005	3,000	140	260	280
Other Macaques	995	520	420	440	470
Tamarins*	2,190	810	311	407	460
Common marmoset	170	170	38	120	120
Owl monkey	1,465	150	26	60	105
Chimpanzee	180	180	48	69	90
Gibbon	100	20	5	5	10
Baboon	1,282	100	17	190	190
African green monkey	2,075	200	57	110	200
Squirrel monkey	4,445	800	260	365	445
Other	990	460	364	400	415
TOTALS	33,912	15,410	4,746	7,666	10,785

*Saguinus species

BIOMEDICAL RESEARCH SUPPORT PROGRAM VERSUS CAPITATION PROGRAM

The President, as you may know, has proposed that we cut back drastically in funding for capitation programs for schools for health training.

Question: Is there any connection between your biomedical support funding which the institutes and schools can use rather loosely and the capitation program?

Answer: The captiation program is for the support of health professional education, that is, the education of persons to provide clinical care. Capitation funds are not intended for support of research or research training. Biomedical Research Support Grants are awarded under the health research authority of the Public Health Service Act (Section 301c), and cannot be used for education of any kind. Grantee institutions cannot use Biomedical Research Support Grants loosely, even for health research, because the program emphasis is upon those health research needs that are not feasibly supported by other Public Health Service grant programs, and which are supported most efficiently and at least cost with Biomedical Research Support Grants. In fact, Biomedical Research Support Grants program guidelines are quite specific about allowable research uses of these funds.

REVISED BIOMEDICAL RESEARCH SUPPORT POLICY

Last year, NIH engaged with the White House and OMB in a reexamination of policies governing the allocation of resources in the Biomedical Research Support program.

Question: What were the results of this study?

Answer: The policies governing the use of funds in the Biomedical Research Support Grant Program were largely reaffirmed. Three changes in those policies were agreed upon and will become effective April 1, 1979. Those changes are:

1. The intent of the Program to benefit primarily research to develop new knowledge about fundamental processes related to health is made explicit by imposing a requirement of prior approval by NIH to allocate less than 90 percent of any one grant for this purpose.

2. Support of foreign travel is prohibited.

3. Limitation on the use of Biomedical Research Support Grant funds for research salary of any one tenured faculty or equivalent scientist is extended from a cumulative total of six months in any two consecutive grant years, to a cumulative total of six months in any four consecutive grant years.

Question: How have these results been translated into your fiscal year 1980 budget request?

Answer: Funding for the Biomedical Research Support Grant program was again requested by the Administration, at the same level as 1979, to continue to meet important needs in grantee institutions.

MINORITY BIOMEDICAL SUPPORT INDIRECT COSTS

Last year for the first time, the Committee provided funds to reimburse medical schools for indirect costs incurred from participation in the Minority Biomedical Support program.

Question: What has been the reaction to this program from these institutions?

Answer: Currently 69 institutions receive Minority Biomedical Support awards. These include 6 medical schools as well as graduate and undergraduate schools. The institutional leaders are pleased that their institutions are receiving the same treatment accorded other institutions receiving competitive Federal research grants. The payment of indirect cost allows compliance with Department of Health, Education, and Welfare policy of reimbursing grantee institutions for all costs incurred in their research efforts.

Question: What is your budget request for this in 1980 as compared to 1979?

Answer: Our budget request for 1980 is $256,000 less than the 1979 budget. The indirect cost rate is estimated to be at or about the same level as 1979 and will require about $3.5 million of the requested $14.3 million budget.

NEW TECHNOLOGY AND EQUIPMENT FOR BIOMEDICAL RESEARCH

Question: As we make more and more advances in the area of biomedical research, what needs and contributions are being made from the Division's standpoint in terms of new technology and equipment to better improve our biomedical research?

Answer: In the fall the Division's staff and scientific advisors identified needs for new biotechnology resources in a number of areas. These needs are based on the current state of and projected advances in technology and the uses and applications of the technology in biomedical and clinical research. Based on these recommendations and on high priority approved unfunded grant applications the needs for new biotechnology resources are:

1. A resource to facilitate and develop biomedical applications of synchrotron radiation. The National Science Foundation and the Department of Energy have made long-term commitments to developing synchrotron radiation facilities for research applications in physics, chemistry and materials science. This radiation has unusual properties which could be used to solve important biological research problems in areas of muscle structure and function, segmental motion in proteins, and chemical reactions related to vision.

2. Laser microbeam radiation is also being used to study cellular function, and a regional resource in this area is needed.

3. High resolution nuclear magnetic resonance to display images of hearts and other organs and tissues. This technology has great medical promise as a non-invasive technique which is

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complementary to the established x-ray imaging techniques.

4. Computer resources for simulation of organ function to permit testing the effects of drugs and other treatments on the computer before giving them to patients. A similar effort on the DRR developed PROPHET computer resource now allows research scientists to test the effects of proposed new drugs by comparing known drug responses for similar compounds. The American Chemical Society has scheduled three full days of presentation and discussion in the area of computer-assisted drug design for a meeting this spring; researchers in the drug industry and universities will be involved.

Over 700 projects supported by the NIH categorical Institutes made use of biotechnology resources during Fiscal Year 1977. Results of a number of these projects have been reported in the Research Resources Reporter, a document published monthly by DRR and distributed nationwide to the NIH community. These projects apply current resource technology to solve biomedical and clinical research problems. The DRR funded Biotechnology Resources also develop new technology needed in biomedical and clinical research. Examples of these contributions are given below:

1. Development of the computer hardware and software and electronic hardware for the positron emission transaxial tomograph (PETT). This was first completed in the Biotechnology Resource at Washington University, St. Louis, Missouri. The PETT now in its fourth design phase is used for diagnosis of intercranial lesions.

2. Development of a computer system to analyze 24 hour ambulatory electrocardiograms for use in studying dysrhythmias (irregular heart beats), anti-arrhythmic drugs and new therapeutic techniques to protect the myocardium (lining of the heart).

3. The availability of stable isotope (non-radioactive) enriched drugs and metabolites from the National Resource at Los Alamos, funded by the Division, has allowed studies of normal and abnormal metabolism in children and other patients without the risks involved when radioactive isotopes are used.

DIVISION OF RESEARCH RESOURCES PROGRAM PRIORITIES

Question: If you had to pick what your top priorities were in the Division, Dr. Bowery, what would they be?

Answer: Top priority would be given to research grant awards for several key areas within our research resource programs. These are set forth below.

Within these overall priorities, our funding decisions will continue to take into account as a primary factor the scientific quality (the priority score) of the resource. In addition, other major factors such as the degree of intra- and extra-institutional scientific collaboration evidenced and the cost-effectiveness of the resource program are also considered.

Of highest priority is the need to stabilize and strengthen the Division's investment in nationally shared research instrumentation facilities. These are the Biological Structure and Function research resources of the budget activity designated Biotechnology Research. This group of resources provides biomedical investigators access to specialized techniques such as mass spectroscopy, nuclear magnetic resonance spectroscopy, electron spin resonance spectroscopy, biomedical kinetics studies, electron microscopy, and electron microprobe analysis for the study of structure and function of complex biological systems.

The second area of priority is the need to stop the erosion of the research bed capacity and capability of the Division's Clinical Research budget activity. The over 600 beds specifically dedicated for extramural research projects of the General Clinical Research Centers Program represent close to 75% of the NIH investment in such beds and highly trained support staff within the Nation's teaching hospitals. These research beds serve as a necessary undergirding research resource for the clinical research investigators funded by the categorical Institutes of the NIH, and represent a critical and necessary environment for the translation of many basic research findings into better patient care.

The third top priority area is that of the Biomedical Research Support Program. This is a program of flexible funds for institutional self-determined allocation for biomedical research purposes. Close to 500 institutions operate within the Divisional guidelines that emphasize the funding of pilot basic research projects for new and young investigators and the development and maintenance of effective and efficient shared central research resources. This program has proven to be an extremely valuable and cost effective mechanism to modulate the stresses and strains on biomedical research activities of the Nation's institutions that are most active in biomedical research.

JOHN E. FOGARTY INTERNATIONAL CENTER FOR ADVANCED STUDY IN THE HEALTH SCIENCES

STATEMENT OF LEON JACOBS, DIRECTOR

ACCOMPANIED BY:

DONALD S. FREDRICKSON, DIRECTOR, NIH
NORMAN D. MANSFIELD, DIRECTOR, DIVISION OF FINANCIAL MANAGEMENT, NIH
WILFORD J. FORBUSH, DEPUTY ASSISTANT SECRETARY BUDGET, DHEW
KENNETH S. LEVINE, DEPUTY ASSISTANT SECRETARY FOR LEGISLATION, DHEW

BUDGET REQUEST AND PREPARED STATEMENT

Senator HATFIELD. Our final witness is Dr. Leon Jacobs, the new Director of the John E. Fogarty International Center.

Dr. Jacobs, your budget request is the same as last year's level, according to my record, $8.9 million.

I will place your printed statement in the record.

[The statement follows:]

STATEMENT OF LEON JACOBS

Mr. Chairman and members of the Committee:

This is my first appearance before you to present the programs of the John E. Fogarty International Center for Advanced Study in the Health Sciences. I am very pleased to do so. I had an opportunity to meet Congressman Fogarty 15 years ago, and I could not help but be impressed with his dedication to the health sciences. It is, I believe, appropriate that Congress resolved for the creation of an International Center, with his name, within NIH. He had an appreciation of the universality of science. FIC is a tribute to a truly benevolent man in the environment of NIH, which he fostered.

NIH was involved in international research programs prior to 1968, when FIC was created. Public law 86-610 authorized the exploitation of collaborative research opportunities abroad. Public law 480 authorized the use of excess foreign currencies for health research. NIH also provided grants to exceptional foreign scientists for biomedical research. There was also a program for the award and administration of international fellowships of various types. These programs were coordinated in an Office of International Research.

In order to fulfill the ambitions of Congress and ourselves when FIC was created, a number of new activities were launched and old ones extended. The Fogarty Scholars program was one of those added. This provided for senior distinguished scientists from the U.S. and abroad to spend up to one year studying and working on the NIH campus, and contributing their knowledge to other research centers. The interaction of these brilliant minds with their counterparts in Bethesda and in universities has been very fruitful in the stimulation of new ideas in a variety of fields. Another new initiative was the development of a series of advanced studies on issues related to health systems of other countries; on preventive medicine; on legal, ethical, social and economic issues related to biomedical research and its application; and on new research concepts. The fabric of these studies was, and is, of a different nature than laboratory bench science. It is analysis and synthesis, consisting of bibliographic research, seminars and workshops and conferences involving Fogarty scholars and other distinguished contributors from different nations, study by FIC staff and by invited experts. Still another new but more recent program, suggested by Senator Magnuson, is one of senior international fellowships which provide opportunities for established American investigators to work and study abroad. In addition, FIC has become increasingly involved in the administration of NIH's overall relations with governments of other countries on science, health, and biomedical research.

These programs were expanded or created during the first ten years of the existence of the Fogarty International Center. Because I have only recently become its Director, I can say without appearing immodest that FIC has made important contributions in advancing health research. The next few years will see continually increasing responsibilities in, for example, establishing collaboration with the scientists of the People's Republic of China, in strengthening existing ties and furthering collaboration with developing nations in Asia, Africa, and South America, and in enhancing research collaboration with the developed nations of the world. We also see opportunities for new advanced studies on our own part.

Let me describe the programs I have already mentioned and the others we conduct as they now are operated.

The Fogarty Scholars are chosen on the basis of the distinction they have achieved in their own research and on appraisals of their ability to interact with and lead others in a series of scholarly endeavors. The nominations can be made by NIH staff or by scientists in other institutions. A committee composed of senior scientists at NIH makes the final recommendations for selection. The Scholars are provided with offices and secretarial help. They are encouraged to

set up their own seminars and workshops and to interact with scientists at NIH and elsewhere. They also are given the opportunity to organize international conferences on new and emerging areas of science. FIC conference logistical support is provided to them, and other Institutes and Divisions at NIH are invited to participate in the conduct and financial support. Last July, for example, a very important and stimulating conference on membranes and their role in biological recognition was held under the aegis of two Fogarty Scholars and one intramural scientist. It attracted participation by scientists in a variety of fields, ranging from microbiology to hormones to cancer immunology, and was highly successful. The subject is of enormous biological importance.

At present, we have four Scholars on the NIH campus. By June, we will have six more. We would like to have as many as 15 Scholars "on board" at any one time, but this is not always feasible. For this program, we expended $312,000 in F.Y. 1978. We expect the same level in 1980.

I have already described briefly the types of advanced study that have been conducted and supported by the FIC. This work has resulted in a series of publications on health organizations and systems in other countries, including the USSR and the People's Republic of China. Books, such as "Medicine and Public Health in the People's Republic of China," "Chinese Herbal Medicine," and "Medicine in Chinese Cultures" have been published by FIC. These provide us with useful orientation towards our further cooperation with the PRC now that the U.S. and the PRC have entered into new relations. FIC is serving the Director, NIH as the focal point for the development of cooperative programs with the PRC, as we do for other bilateral agreements with, for example, France, the Federal Republic of Germany, Italy, Egypt, India, the USSR, Poland, Yugoslavia, and Romania.

Advanced study programs in FIC are being shifted from health care to themes of broad scientific interest to a number of NIH components. We hope to encourage and support a study of medical genetics as it relates to anthropology, studies on animal models of disease, and a series of others, in a variety of ways. For example, one of our recent Fogarty Scholars is especially interested in animal models of diabetes and obesity. He can serve as the stimulus for work in this area. Another Fogarty Scholar is especially interested in the biological basis of metastasis, or spread, of tumor cells from the original site of a tumor to other organs. This subject will be of great interest to cell biologists working not only on cancer but on other diseases. In all of these enterprises FIC consults with and involves the other Institutes and Divisions of NIH. We will study health care on the international scene only from the standpoint of gaining an appreciation of the impact problems in health care have on biomedical research direction and policy.

The fellowship programs of FIC continue to be among its most rewarding activities. The International Research Fellowships Program provides opportunities to young foreign scientists to engage in collaborative research with U.S. scientists in leading universities and institutions. National committees nominate individuals they consider competent and promising. The nominations are then reviewed here, as to the qualifications of the candidates, significance of their proposed research and the suitability of the laboratories selected.

From the inception of this program thru 1978, 1708 fellowships have been awarded. We have received many unsolicited favorable comments from U.S. scientists about the value of the program. Recently, we undertook an evaluation of its effect in the approximately forty countries that participate and on biomedical science in general. We traced the careers of the fellows and convened two conferences to bring together some American preceptors and chairmen of the countries' nominating committees. The results indicate that most of the fellows, at least 80%, have continued in research or education, and they have published over 27,000 papers in respected journals in their own and other countries. Most of the fellows have

advanced academically and many have become leaders. Many of them have continued to collaborate with U.S. scientists. In fiscal year 1978, we awarded 128 international research fellowships. Because we have had to increase the stipends due to rising living costs, we expect to be able to award 106 fellowships in F.Y. 1979 and in F.Y. 1980.

In fiscal year 1975, FIC announced a new senior fellowship program to provide opportunities for established American scientists to work and study abroad. The response has been enthusiastic, and we receive applications of high quality. Since its beginning, the program has awarded 179 fellowships, 29 in F.Y. 1975, 33 in F.Y. 1976, 53 in F.Y. 1977, and 64 in F.Y. 1978. Here again, because we have had to increase stipends and living allowances, we anticipate that we will be able to award fewer fellowships in F.Y. 1979, and F.Y. 1980, about 46.

Included in the F.Y. 1979 appropriation is $200,000 for special international research fellowships in aging. We are working with other Institutes to provide special fellowships in the neurosciences, tropical diseases, diabetes, arthritis, and other fields.

In addition to conferences originated by Fogarty Scholars, which I have already mentioned, FIC cooperates with NIH Institutes and Divisions, and with other agencies, in the review of conference proposals which are received from scientists around the country. If a proposal is approved, FIC staff coordinates funding and management of the conference. During F.Y. 1978, FIC participated in supporting and managed 17 conferences on the NIH campus. FIC also participated in the support of 54 conferences held elsewhere. In F.Y. 1978, 85 books and reports, stemming from scientific meetings of various types, were published or in preparation. It is anticipated that approximately the same level will be maintained in F.Y. 1979 and F.Y. 1980.

In addition to these functions, FIC cooperates with the WHO in arranging for short-term training of allied health fellows from many countries funded by WHO, in various institutions in the U.S. In F.Y. 1978, FIC provided services to 244 such fellows. FIC also arranges for the review of biomedical research projects to be funded under the U.S.-Egypt joint agreement with special foreign currencies (PL 480) and by the U.S.-Poland Joint Fund. FIC also is responsible for projects using PL 480 funds in India and Pakistan.

FIC also serves as the administrative channel by which funds appropriated by the Congress are made available to the Gorgas Memorial Institute for the maintenance and operation of the Gorgas Memorial Laboratory in Panama. FIC has no administrative responsibility for GML but maintains surveillance of its activities with respect to this funding.

Another function of the FIC is the administrative management of the NIH Visiting Program for the NIH. The purpose of this program is to invite distinguished and talented scientists at all levels of their careers to NIH for an interchange of scientific information and training. During 1978, 862 scientists participated in the NIH Visiting Program, supported by $10.2 million of NIH funds. Of this total, 675 scientists were from 55 foreign countries accounting for $7.3 million of the total expenditure. A full range of advisory and facilitative services are provided to these and some 350 other scientists who come to participate in NIH research activities.

I want to emphasize that the mission of FIC is to advance international biomedical research thru the various activities mentioned above. We can do this best by also maintaining our own intellectual entity in the research enterprise.

For these programs and activities, FIC is requesting $8,989,000, the same level as in F.Y. 1979. I shall be pleased to reply to any questions of the Committee.

PROGRAM HIGHLIGHTS

Senator HATFIELD. I wonder if we could proceed immediately to the basic questions here, which will give you an opportunity to probably refer back to the statement as well.

I wonder if you could just, primarily for my edification, highlight your program as to what you consider to be the most effective parts of the program over the last few years, as far as those areas which have contributed to the advance and contributions of biomedical research in this country?

Dr. JACOBS. The things I would highlight, Mr. Chairman, are the scholarship and fellowship programs, and the conferences and seminars which result from the scholarship program, because of the scholars who come there and organize their own conferences.

You must know from your own years in academic life what the synergism of creative minds produces in the way of sparking new ideas and new approaches to problems.

That is what our conference program is specially involved in.

I may perhaps point out to you that we have a very small scholars program. We have in the budget enough for about seven scholar years per year. That means we can support scholars, as residents at NIH, working at NIH, up to the number of eight now. Some of them don't come for so long, so that individually we may have as many as a dozen in a year, because some come for 6 months.

First of all, they are nominated by scientists inside and outside of NIH. Scholars themselves sometimes nominate other individuals to be scholars.

The nominees are all very distinguished people. Some of them have been Nobel laureates. Those that are selected and accept come and interact with NIH staff. We also provide them with the opportunity to visit other institutions around the country if they so desire.

Senator HATFIELD. Excuse me. Do you make the final selection?

Dr. JACOBS. The selection is made by a committee of NIH senior staff members, directors and scientific directors of institutes, and some of the top scientists of the NIH.

The criteria for selection are that they are distinguished, they have made various contributions to their areas of research, that they are the types of individuals who will interact with many different scientists at NIH and elsewhere.

I can tell you that, we have only four on board at the moment. We expect to get two more by June, and we will have a total of ten for a few months in the fall.

We have a great deal of activity going on. Seminars involving the scholars and NIH staff, meeting regularly at NIH, and approaching some very, very fundamental problems about biochemical research and research in cellular biology are being held

So, I regard this as a really special program. Even though it is small, it has the capacity to generate a great deal of information in basic research areas.

INTERNATIONAL RESEARCH FELLOWSHIPS

Dr. JACOBS. Now, beyond the scholars, we have fellowships, which we have going both ways.

First of all, we have international research fellows who come from other countries to this country, and they interact with American scientists, and after a year, sometimes with some extensions, they go back to their own countries. We have just conducted an evaluation of the value of this program over the last 20 years.

We have had some 1,700 fellows in that period of time. Eighty percent of them are still engaged in biomedical research, either full or part time. Most of them are in academia, or in medical research institutions.

They have published over 17,000 research papers in respected journals in their own countries, and in other countries.

So, we have made a real contribution to biomedical research in general by doing this, because there is a lot of collaboration between the individuals with whom they have worked here and the individuals who are now overseas.

And I can point out to you the names of individuals who were fellows years ago, who are now the directors of medical research institutions in other countries.

For instance, the director of INSERM, which is the principal government medical research agency in France, is a former international research fellow.

OTHER RESEARCH CENTERS

Senator HATFIELD. Are there other centers like this in other parts of the world, in which there are scientists who travel and study?

Dr. JACOBS. Let me answer that a little bit indirectly. Because I can't identify places where the same type of activity goes on, as goes on here, except for three institutions.

The Swiss National Science Foundation, and the Swedish Medical Research Council have, for a number of years, granted fellowships to American scientists to go over there. Actually that was stimulated in response to our program.

Ten or twelve young American postdoctoral scientists go overseas every year, and they are funded by these organizations. These organizations do the same job that we are doing, identifying preceptors and places where these young people can work.

France, under the stimulus of our alumnus, is about to start a similar program. So that there is an interaction.

CONFERENCE PROGRAMS

Dr. JACOBS. Now, beyond that are the conference programs, which we have supported with the collaboration of most of the other institutes at NIH. We hold conferences on a variety of subjects, which are of interest to many of the institutes at NIH.

For instance, we just got through with one on pain, the management of pain. Now, this originated in Dr. Fredrickson's Office of Medical Applications of Research, which is oriented toward trying

to develop the extension of biomedical research findings to application.

We in the Fogarty Center and some of the other institutes sponsored this conference to determine the best techniques for the management of pain.

There have been a number of other conferences——

CONFERENCE ON PAIN

Senator HATFIELD. How many participants were involved in that?

Dr. JACOBS. We had a preregistration that was so big that we expected to have to use auxiliary rooms and closed circuit television

Senator HATFIELD. By invitation?

Dr. JACOBS. By invitation and announcement.

It so happened that it was held right after the heavy snowstorm. Isn't that right?

Dr. FREDRICKSON. Yes, that is right.

Dr. JACOBS. The 2-foot snow. The attendance came down, but it was still enough to occupy the large auditorium.

Senator HATFIELD. Were there some foreign persons involved in this?

Dr. JACOBS. Yes.

Senator HATFIELD. Were your resource people only Americans?

Dr. JACOBS. The resource people were foreigners as well as Americans.

Senator HATFIELD. How long did the conference last?

Dr. JACOBS. Two days.

Senator HATFIELD. Now, do you pay for certain expenses of the individual participants, observers, or only panelists or what?

Dr. JACOBS. We will pay the travel and per diem expenses of invited participants.

FOGARTY CENTER AS A RESOURCE

Dr. FREDRICKSON. This conference, Senator Hatfield, included sponsorship from the ADAMHA, the National Institute of Mental Health, and the Bureau of Drugs of FDA. It was a truly ecumenical exercise to bring all the people and the resources to focus upon a particular problem.

The Fogarty Center is our expression of the universality of science. It is truly international, and without this kind of an organization to facilitate international cooperation, I think we would be far less efficient than we are.

CONFERENCE COSTS

Senator HATFIELD. Could you give me a ballpark figure on what that conference costs in terms of your budget?

Dr. FREDRICKSON. The conference was not funded by Fogarty, but by sponsoring institutes——

Dr. JACOBS. I would estimate the average cost of a conference is around $17,000 or $20,000.

Dr. FREDRICKSON. Fogarty does not sponsor this from its own budget, but it is a central coordinator.

Senator HATFIELD. That is very helpful.

Thank you very much, Dr. Jacobs.

Well, this has been a very enlightening hearing for me. I really appreciate it, Dr. Fredrickson.

Thank you very much.

Would you folks have something to say? You have not been permitted at this point to say anything, but you are welcome to comment, any of you folks at the table here.

I would like to have the response to these questions back in a week, if that is possible.

Well, thank you again for your fine testimony, and your assistance this morning. It has been very helpful.

[The following questions were not asked at the hearing, but were submitted to the Department for response subsequent to the hearing:]

STABLE BUDGET LEVEL

Question. The budget level for the Fogarty Center has been quite stable for several years now in terms of very few increases. What effect has this had on the Center?

Answer. Although there has been some special increases such as increases for the Gorgas Memorial Institute and an allowance for special international fellows in the field of aging, the Center has had relatively stable budgetary levels. There has been some erosion due to inflationary costs. For instance: new stipend levels for the Scholars and Fellows require increases in each fellowship award and, therefore, fewer numbers of fellows can be supported.

PRIORITY AREAS

Question. What programs are your highest priority areas right now?

Answer. We feel it important that scholarships and fellowships be supported as much as possible, as well as conference activities and bilateral exchange activities with other countries.

FOGARTY AGING PROGRAM

Question. As I am sure you are aware, last year Senator Magnuson put additional funds into the Fogarty International Center budget for international training programs in the area of aging. Do you have any comments on this program, and is it operative as of this date?

Answer. Yes, the emphasis on aging has been incorporated into the senior international fellowships program, also known as the Magnuson International Fellowships. We published an announcement of this special emphasis program in the NIH Guide for Grants and Contracts on December 15, 1978. The National Institute of Aging has also published announcements in specialized journals. We have already received some 20 applications for special emphasis fellowships and after review will award approximately seven fellowships for work in the aging area.

PAN AMERICAN HEALTH PROGRAMS

Question. What developments have transpired with regard to the relationship between the Center and the Gorgas Memorial Institute?

Answer. The finalization of a formal agreement covering the various facets of the relationship between the Fogarty International Center and the Gorgas Memorial Institute awaits reaching a mutually acceptable understanding primarily on the extent to which the funds for the Institute are subject to the same review and budget processes that are required of other funds of the Center and NIH. This question has been reviewed in considerable detail by officials of NIH and DHEW over the past months and we expect to meet with Institute officials on March 7, 1979 to develop a position which is satisfactory to the interests and requirements of both parties. The lack of a formal agreement has not precluded what we consider to be a close and harmonious on-going relationship with the Gorgas Memorial Institute which permits the Center to fulfill its responsibilities for program oversight with respect to the use of Government core support funds and which at the same time respects the independent and private nature of the Institute.

FUNDING FOR GORGAS MEMORIAL INSTITUTE

Question. How much are you providing in terms of funding in fiscal 1980 and how does this compare to past years?

Answer. The President's budget request for the Gorgas Memorial Institute in fiscal year 1980 is $1,700,000. The prior appropriations are: fiscal year 1979 $1,700,000; fiscal year 1978 $1,400,000; fiscal year 1977 $1,400,000.

SUBCOMMITTEE RECESS

Senator HATFIELD. We will stand in recess until 2 o'clock.

[Whereupon, at 12:05 p.m., Thursday, March 1, the subcommittee was recessed, to reconvene at 2 p.m. of the same day.]

(AFTERNOON SESSIONS, 2:10 P.M. THURSDAY, MARCH 1, 1979)

NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES

STATEMENT OF RUTH L. KIRSCHSTEIN, DIRECTOR

ACCOMPANIED BY:

DONALD S. FREDRICKSON, DIRECTOR, NATIONAL INSTITUTES OF HEALTH

WILLIAM T. FITZSIMMONS, EXECUTIVE OFFICER, NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES

NORMAN D. MANSFIELD, DIRECTOR, DIVISION OF FINANCIAL MANAGEMENT, NATIONAL INSTITUTES OF HEALTH

KENNETH S. LEVINE, DEPUTY ASSISTANT SECRETARY FOR LEGISLATION

WILFORD J. FORBUSH, DEPUTY ASSISTANT SECRETARY, BUDGET

ETHICS LAW

Senator EAGLETON. Dr. Fredrickson and company, we welcome you and your colleagues, as many times before.

Dr. FREDRICKSON. I believe you are ready for the National Institute of General Medical Sciences.

Senator EAGLETON. Are we going right to the institutes? Have you given an overview? Very good.

First, let me take up a question that is on my mind. I think this is very important. We had Secretary Califano here earlier this week, and we chatted with him about this new ethics law that takes effect when, July 1, is it? The ethics law, and prohibition on Federal employees, your assignment and other various disciplines in the Government, where they would be prohibited from really practicing their profession, et cetera.

Share with me some of your thoughts on that. Because I think it is a problem of significant dimension, and I think it a problem worthy of some discussion. It has to be considered with great promptness. We can't wait until midnight June 30. Some people may say I better start looking for jobs now, or something.

Share with me some of your views on that dilemma.

Dr. FREDRICKSON. Yes, Senator. The law we are talking about is 95-622, the 1978 amendment to the Ethics in Government Act, particularly title V.

There are some words in title V that at the present time, without further interpretation, make it appear that after July 1 most of us are in jeopardy if we leave our positions for new positions in related areas. There is concern about possible conflict of interest between our responsibilities in the Government, and positions we might assume later. In essence, without some assurance of how the law, which is a criminal statute, will be interpreted, many of us are very uncertain as to whether after July 1 we could take the kinds of positions that most people do take when they leave the Federal service.

Senator EAGLETON. You could open up a private practice in some city, but presumably your life has been primarily in research, et cetera.

More than likely, you would want to stay in research.

Dr. FREDRICKSON. We would likely be associated with universities in administrative roles, as professors of departments, deans and so forth. It is clear, that in the wording of this new statute, that there is a lot of risk of criminal penalties, for engaging in even informal consultation.

Senator EAGLETON. Do you know if the administration is analyzing this beyond the totality of HEW? Is somebody at the White House, to your knowledge, taking a look at this?

Dr. FREDRICKSON. Yes. As you know, under the statute, Senator, there is someone appointed to write interpretations, providing administrative views.

At the present time, he has made available a first draft to members of the administration, the Office of Science and Technology Policy. I think this is a very important first step. However, we are not certain how the Department of Justice will look upon this administrative interpretation of the criminal statute, and we need some reassurance there.

There are people who have been advised by good lawyers that without some amendment to the statute itself, they may not escape jeopardy.

Senator EAGLETON. I'm on the Government Affairs Committee. Let's send a letter to Senator Ribicoff and to Senator Byrd summarizing the problem, at least as we know it from this context, and it may have even broader ramifications over and above NIH and HEW. It is a matter of some degree of urgency, because people have to start thinking about their own futures.

Maybe we ought to address the letter to the President, to make sure it gets in the hands of Eizenstat, with copies of the letter to the President to these other fellows.

Thank you, Doctor.

All right. General Medical Sciences.

PREPARED STATEMENT

Dr. KIRSCHSTEIN. Yes. I would like to submit my written statement for the record and summarize the activities of the National Institute of General Medical Sciences, which is the basic science institute of NIH.

[The statement follows:]

STATEMENT OF RUTH L. KIRSCHSTEIN

Mr. Chairman and Members of the Committee:

About twenty-five years ago, a young American research fellow, James D. Watson, and a slightly older English physicist, Francis Crick, published a short article in the British scientific journal, Nature, entitled "Molecular Structure of Nucleic Acid, A Structure for Deoxyribose Nucleic Acid." Watson and Crick were interested in the nature of genes and how they work. Their great contribution, for which they won the Nobel Prize, was to show that DNA (deoxyribonucleic acid), the chemical material of genes, consists of two strands coiled into a "double helix"--admittedly a structure of great abstract beauty, but at that time, certainly not considered by most of us as as a discovery to help sick people. How wrong we were!

Watson and Crick's basic research was, in fact, a precursor and prerequisite of the medical research that is being and will be done in the last quarter of the twentieth century. Most of the diseases that remain to be conquered arise as a consequence of defects or changes in our own genetic and cellular makeup and the expression of such defects in response to environmental factors; these diseases are polygenic or multifactorial such as cancer, atherosclerosis and diabetes. They are very common and yet still mysterious diseases, and, in ways that they, themselves, did not appreciate at that time, in 1953, Watson and Crick mounted the first skirmish in the molecular approach to understanding such diseases. In a separate report to this Committee, the NIGMS summarizes the state-of-the-art regarding polygenic or multifactorial diseases and its plans for future support of studies in this area based on the recommendations of a group of expert consultants who held discussions with the Institute staff in the fall of 1978.

The studies of Watson and Crick also laid the foundation for recombinant DNA technology. This direct outgrowth of their work already has, in a few short years, given rise to the potential for new methods for (1) the manufacture, in bacterial systems, of medically useful proteins such as insulin or growth hormone, (2) the production of safer vaccines, and (3) better, more effective detection of genetic changes in, for example, sickle cell disease.

Today, I am pleased to have the opportunity to emphasize again the essentiality of the National Institute of General Medical Sciences in the support of basic biomedical research, such as that done by Watson and Crick, and its relation to all the other Institutes that together constitute the National Institutes of Health. It is the distinctive and unique mission of he NIGMS to focus its support on such research, without which progress in the diagnosis, treatment, prevention and amelioration of specific diseases (the missions of the other Institutes) would be slowed. It is characteristic of the research supported by NIGMS that, as progress is made, there may be an impact on one or more specific disease entities, such as cancer, heart disease, diabetes, stroke and arthritis. And, just as the impact of such fundamental research may not be obvious on a short time scale, long range it will become abundantly clear.

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Basic Cellular, Molecular and Genetic Studies

While we know that each cell in the human body, of which there are trillions, has a very specific structure, the relationship between this structure and the various cellular functions is still not well understood. But we do know that DNA and its cousin, ribonucleic acid (RNA), are essential to the functioning of all cells.

It is by the process of mitosis that cells divide and pass on their genetic material (DNA). At the time of mitosis, the DNA is condensed into chromosomes, each of which splits in two as the cell divides. It is likely that this normal process of cell division is deranged in a number of diseases, particularly cancer. In order to better elucidate the process of cell division, or mitosis, grantees of the Cellular and Molecular Basis of Disease Program (CMBD) are developing a new series of devices for using laser microbeams which dissect out, segregate and selectively inactivate the various structures involved. If such inactivation prevents the completion of normal mitosis, then it will be evident that a particular structure is essential. Thus far it has been found that, while each of the structures formed during the mitotic cycle is important, no one is so critical that cell division is halted without it. However, what has been shown is that ribonucleic acid (RNA), the material which translates the hereditary message from DNA into the manufacture of proteins, is also essential for mitosis. Further studies using differential inactivation of various cell constituents and organelles may lead to a fuller understanding of cell division.

The DNA which makes up the genes directs a series of different messages to the ribosomes which are responsible for the manufacture of the proteins which are required for the various functions of the cell. A number of grantees of the Institute's Genetics and CMBD Programs are collaborating in a study to map the location of individual proteins on particular ribosomes. This is done by making specific antibodies to the ribosomal proteins, attaching these antibodies to ribosomes, and then studying the preparations with the electron microscope. This immune electron microscopy method is a very specific and sensitive one and from it one can learn more about the location within the cell of particular proteins which are produced not only by normal cells but by diseased cells as well.

Clearly, the nucleic acids, RNA and DNA, are the very "stuff" of which life is made and without which cellular function is not possible. Studies, starting more than 25 years ago and continuing now and well into the future, have shown and will continue to show their universality.

Pharmacology-Toxicology Program

Grantees of the Pharmacology-Toxicology Program are studying the distribution of drugs in the body and measuring drug levels in the various body fluids. Once a drug has had the opportunity to achieve its desired effect, it must be eliminated by the body, either in the intact form or as breakdown products or metabolites. If such elimination does not occur, accumulation of the chemical occurs, markedly increasing the possibility of toxic effects. The major pathways for elimination are through the kidney and/or the liver. Pharmacologists at the University of Kansas have shown that the newly marketed drug, disopyramide, used to treat irregular heartbeat, is eliminated much more slowly by patients with kidney disease than by those whose kidney function is normal. Therefore, the dosage for this drug must be individualized and physicians must monitor the renal function of patients with heart disease in order to use this drug safely. Further research in clinical pharmacology is needed in order to assure that all drugs are used safely and that all aspects of toxicity, including decreased excretion, are understood before therapy is started.

Physiology and Biomedical Engineering Program

In the year since we last reported to this committee, the Institute has merged the activities it supports in physiology, in clinical studies and in biomedical engineering to form a Physiology and Biomedical Engineering Program. This has enhanced the overall effectiveness of the research effort in both of these areas.

Burn Research

NIGMS continues to emphasize support of basic biological research related to the reaction of the whole body to burns and other injuries. Although there remains a great deal to learn regarding the multiple organ system failures which occur following trauma and burns, this past year seemed to be a propitious time to assess the status of supportive treatment of severely burned individuals. In order to synthesize recommendations regarding such treatment and also to determine the most important areas in which research is still needed, NIGMS, in collaboration with the American Burn Association, held a consensus development conference in Bethesda on November 10 and 11, 1978. The conclusions of the meeting, which can be used by practicing physicians as a guide to the care of individual patients, were published in the Journal of the American Medical Association. In summary, the conferees concluded that:

1. The administration of salt and water within the first 24 hours after severe burn injury is the keystone to effective resuscitation.

2. Fundamental questions still remain regarding prevention of infection, stimulation of the body's own defense mechanisms, the role of multiple organ failure and its prevention, the metabolic effects of burn injury, the role of nutrition, and the importance of excision of burned skin and of early grafting.

3. Research in all the above areas is essential for improved therapy, survival, and rehabilitation of the severely burned.

Research Training

As you know, the National Institute of General Medical Sciences is preeminent at NIH in the support of the training of the biomedical research scientists of the future. Of particular concern is the decrease in the number of medically trained persons opting for research careers. The NIGMS, through emphasis on and increased support for its Medical Scientist Training Program, hopes to have some effect on increasing the number of physicians who enter research careers. This program is designed to prepare medical scientists for such research careers through studies leading to the combined M.D.-Ph.D. degree. Support is provided only to students of the highest quality at the finest schools.

Minority Access to Research Careers Program

Another research training program of special note supported by NIGMS is the Minority Access to Research Careers (MARC) Program for college students and faculty of institutions with large numbers of minority students. The MARC Honors Undergraduate Training Program now has 17 participating institutions and 136 students. The first class of college students graduated in June 1978 and about one-half of them have entered graduate school to obtain the Ph.D. degree in some area of biomedical science. Continued evaluation of this program is planned.

Mr. Chairman, in order to support the programs discussed, the budget request for the National Institute of General Medical Sciences is $280,378,000. I shall be pleased to try to answer any questions and to supply additional information as requested.

BASIC RESEARCH

In order to illustrate the importance of such activities, I would like to remind this committee, as I'm sure most people know, that, about 25 years ago, a young American research fellow, James Watson, and a somewhat older British physicist, Francis Crick, published a short article in the British science journal Nature, entitled "Molecular Structure of Nucleic Acid, A Structure for Deoxyribose Nucleic Acid."

Senator EAGLETON. Would you suspend just a moment, please? [Discussion off the record.]

Dr. KIRSCHSTEIN. Drs. Watson and Crick were interested in the nature of the genes and how they work, and their great contribution, for which they won the Nobel Prize, was to show that DNA consisted of two strands coiled into a double helix, which was admittedly a structure of great beauty but, at that time, was certainly not considered by most of us as a discovery to help sick people. How wrong we were.

That basic research finding was, in fact, a precursor and prerequisite for all the medical research that is being and will be done in the last quarter of the 20th century. Most of the diseases that remain to be conquered arise as a consequence of defects or changes in our genetic and cellular makeup, and the expression of such defects in response to environmental factors. The work that Watson and Crick did mounted the first skirmish in the molecular approach to understanding such diseases. In a separate report to this committee, at your request, we have summarized the state-of-the-art regarding polygenic diseases, and the plans that NIGMS has in mind for future support of this area.

The studies of Watson and Crick also laid the foundation for recombinant DNA technology. This has already given rise to the potential for new methods for the manufacture in bacterial systems of hormones, such as insulin, and growth hormones, for the production of safer vaccines, and for better detection of genetic changes in, for example, sickle cell disease. It is the distinct and unique mission of NIGMS to focus its support on such research without which the prevention of specific diseases, which relate to the missions of the other institutes, would be slowed, and it is characteristic of the research that we support that, as progress is made, there may be an impact on one or more specific disease entity, such as cancer, heart disease, diabetes, stroke, and arthritis.

Just as the impact of such fundamental research may not be obvious on the short-term scale, long range it becomes abundantly clear, and this is attested to by the fact that 39 Nobel Prize winners have been or currently are grantees of the National Institute of General Medical Sciences.

Senator EAGLETON. How many?

Dr. KIRSCHSTEIN. Thirty-nine.

CELL BIOLOGY AND GENETICS

We know from the studies of such people that DNA and its cousin, RNA, are essential to the functioning of all cells, and are indeed the very stuff of which life is made.

Senator EAGLETON. What page are you on?

Dr. KIRSCHSTEIN. I am summarizing my statement, Senator, at the suggestion of the staff. I'm on page 4.

RNA and DNA will continue to show their universality. Studies of cell biology and genetics are really the basic studies that are supported by the National Institute of General Medical Sciences.

PHARMACOLOGY-TOXICOLOGY

In addition, we have a pharmacology and toxicology program in which studies about the distribution of drugs in the body, the measurement of drug levels and the mechanism of drug action is stressed.

For example, if elimination of a drug cannot occur by either the kidney or the liver because of diseases of those organs the dosage of the drug must be individualized and physicians must monitor either the renal or the hepatic function of the patient in order to be able to use such drugs. Further research in clinical pharmacology is needed and will be stressed by the National Institute of General Medical Sciences, in order to assure that all drugs are used safely, and that all aspects of toxicity, including possible decreased excretion, are understood before therapy is started.

BURN RESEARCH

In addition, the National Institute of General Medical Sciences continues to emphasize support for basic biological research related to the reaction of the whole body to burns and other injuries. There is a great deal more to be learned concerning the multiple organ system failures that occur following trauma and burns, but, in this past year, NIGMS, in collaboration with the American Burn Association, held a consensus development conference in Bethesda. The conclusions of that meeting, which can be used by practicing physicians as a guide to the care of individual burn patients, were summarized, and published in the January 26 issue of the Journal of the American Medical Association, and are available for all physicians as a mechanism of guiding them in the care of such patients.

TRAINING PROGRAMS

The National Institute of General Medical Sciences is the preeminent institute at NIH in the support of training of the biomedical research scientists of the future. Of particular concern is the decrease in the number of medically trained persons opting for research careers. The NIGMS through emphasis and increased support for its medical scientist training program hopes to have some effect on increasing the number of physicians who enter research careers. This program is designed to prepare medical scientists for such research careers through studies leading to the combined M.D.-Ph. D. degree. Support is provided only to students of the highest quality at the finest medical schools.

Another research training program given special emphasis by our institute is the minority access to research careers program for college students and faculty of institutions with large numbers of minority students. The Marc honors undergraduate training pro-

gram now has 17 participating institutions and 136 students. The first class of such college students graduated in June 1978, and about one-half of them have entered graduate school to obtain a Ph. D. degree in some area of biomedical science.

In order to support all of these programs in basic biomedical science and research training, we are requesting a budget of $280,378,000.

I would be pleased to answer questions and supply any additional information.

Senator EAGLETON. Very good. A good deal of your money is going to various training programs.

Would it be fair to say, with respect to the moneys that do not go into various training programs, that those moneys go into basic research, as contrasted with applied research?

Dr. KIRSCHSTEIN. In our institute, that is correct, Senator.

NOBEL LAUREATES

Senator EAGLETON. That causes me, Dr. Fredrickson, to ask you this.

Do you recall a year ago January, we had, I thought, one of the most interesting hearings that I've ever participated in. I think it went on for 4 or 5 hours.

We had an eminent panel of scientists, some Nobel winners, a very distinguished group.

Senator Brooke, and maybe somebody else was there, probed this thorny question of how much research is basic and how much is applied.

Recalling that hearing, and now it is a year later, what update can you give me, Doctor, in the overall?

Dr. FREDRICKSON. Yes, that was an interesting and useful hearing. We all got sort of on the same terms with respect to describing how we fund basic research, how we define it.

In fact, at that time we talked about certain ways we have of allocating our resources.

I think the quickest summary statement that I can give you is that we are funding in this budget just about the same percentage for basic research, and practically the same amount in absolute dollars as 1979.

That is in terms of how we define basic research.

Senator EAGLETON. So about the same in 1980 as 1979. But in 1979, did more go to basic in 1979 vis-a-vis 1978?

Dr. FREDRICKSON. Yes; it did.

BASIC RESEARCH

Senator EAGLETON. Do you think that the direction, not in terms of congressional intent but do you think the facts, circumstances and conditions warranted tilting the thrust a bit more to the basic?

Dr. FREDRICKSON. Yes. I certainly did then, and I do now believe that. I think we needed that increase.

I think we used it wisely. I think we are looking for stabilization as best we can in this time of austerity.

Senator EAGLETON. With that emphasis on basic in mind, Dr. Kirschstein—since your institute is totally tilted toward basic,

whereas when we get into these other institutes, the mix of basic and applied will vary—wouldn't those who are very interested in basic research, if that is our bias, wouldn't we want to add some more money to your institute? You have requested $3 million more than last year—I know you have to support the budget.

But if some Senators say we've got to pick a way to get more moneys into basic research, we couldn't do better than your Institute, could we?

Dr. KIRSCHSTEIN. My prejudices would agree with you, Senator.

Senator EAGLETON. Of course, your Institute does not have the political clout that other institutes have.

I say that advisedly. Some institutes have more clout in the American marketplace, and I understand that.

The very name of your institute hurts you—General Medical Sciences. Nobody can get up and give a stirring Gettysburg address on that.

Dr. Kirschstein, I'm interested in this comment at the bottom of page 6:

> As you know, the General Medical Sciences Institute supports the training of the biomedical research scientists of the future. Of particular concern is the decrease in the number of medically trained persons opting for research.

Can you elaborate on that, as to what that trend seems to be, and what we should do about it, if anything?

Dr. KIRSCHSTEIN. We think that it is a very serious trend. About 5 years ago, it is estimated, about 40 percent of all the scientists who received research grants from NIH were physicians. Currently, it is about 18 percent.

Senator EAGLETON. How long ago was the 40 percent?

Dr. KIRSCHSTEIN. About 5 years ago.

Senator EAGLETON. Less than half, from 40 to 18?

Dr. KIRSCHSTEIN. That is right. There are probably a number of reasons for this.

Among them, the fact that, as tuition to medical school and the cost of going to medical school rises, the individuals, when they graduate, have to find ways of recouping the losses which that may entail.

Second, the new National Research Service Act, which is the training act, has the requirement that there be a payback for the time trained by spending time in research.

Now, an individual who is trained primarily as a biomedical researcher, with a Ph. D degree, has planned a research career for the rest of his life.

An individual who is trained medically has a choice to make, whether to go into practice, academic medicine, or to go into research.

The payback provision may push him away more likely toward a career of medical practice.

We think it is very important to try to increase the number of individuals with medical training who will go into research.

In addition to the Ph. D's, these individuals bring a perspective which is very important to research.

MEDICAL SCIENTIST TRAINING PROGRAM

It is for this reason that we are emphasizing the medical scientist training program. Indeed, the National Academy of Sciences Committee, which has been doing a manpower study, has suggested that such a program be emphasized, and that the number of trainees be increased.

Senator EAGLETON. I perceive a dilemma in the age of skyrocketing tuition. Georgetown Medical School's tuition, I think I read, is $12,500.

Others are up in the multithousand range. And that is a payback situation at Georgetown.

They can borrow the full amount, and have to pay it back.

So, that almost forces a graduate to say, "I've got to go out and get into the more lucrative side of this business, because I've got that loan to pay back."

Now, this program, the medical scientist training program, how does that work? Is there a payback provision?

Dr. KIRSCHSTEIN. Yes; there is. But these people are trained as what we call medical scientists. They get a combined M.D.–Ph. D degree. They are selected by the medical schools that have such training programs because of their specific interest in research, and because they are the most highly qualified students. So that the selection process leads to individuals who will stay in research.

The payback is in research time, unless they do not end up in research, in which case the payback is in funds.

I should say that there is one other thing that has caused a problem to physicians entering a research career, and that is that currently the stipends for trainees at the postdoctoral level are lower than the pay that residents receive for medical training in hospitals. NIH is considering an increase in these stipends, as was suggested in the last renewal of the National Research Service Act.

Senator EAGLETON. How many students are participating now in this medical scientists training program?

Dr. KIRSCHSTEIN. Currently 572 at 23 institutions, in medical schools throughout the United States.

We estimate that we will increase that number to 650 by the end of this fiscal year, and we hope to increase it to 675 during fiscal year 1980.

We also hope to make at least one, and possibly two more awards, so we will increase the number to somewhere around 24 or 25 medical schools.

Senator EAGLETON. The vast bulk of these 572 more than likely will pursue the research route?

Dr. KIRSCHSTEIN. Yes, sir.

Senator EAGLETON. Is this going to, in time, rectify that statistic of 40 percent 5 years ago, 18 percent now?

Dr. KIRSCHSTEIN. This number cannot rectify that statistic by itself.

SHORT-TERM TRAINING

Senator EAGLETON. What else should we do?

Dr. KIRSCHSTEIN. Well, one of the new provisions of the National Research Service Act is for short-term training, allowing training

for 3-month periods without the requirement for payback either in funds or in time in research. Medical students who early in their years in medical school could be enticed into research by having 3-month periods working in the laboratories of some outstanding investigators might be stimulated therefore to enter research careers.

I think we are all very anxious to set up such a short-term training program, but within the limited funds available, it would be very difficult.

Senator EAGLETON. In your thinking of this, have the rough outlines of the proposal been reduced to writing by you?

Dr. KIRSCHSTEIN. Yes. I have more than a rough outline. I have an outline of a proposal for a 3-month training plan for medical students, adding short-term trainees onto already existing training grants, to increase the numbers for these short-term periods, so that this could be put into place very quickly if the funds were available.

Senator EAGLETON. Would you make that proposal available to us? I'm asking for it.

Dr. KIRSCHSTEIN. We would be pleased to. Dr. Fredrickson has, within his office as a special assistant, an individual who is working full time on the problems of research training, and is coordinating these efforts.

Dr. FREDRICKSON. We would be glad to provide that to you.

[The information follows:]

SHORT-TERM SUPPORT FOR STUDENTS WITHIN AN INSTITUTIONAL SETTING

The National Institutes of Health would propose to use the NRSA provision for exemption from the payback obligations of the Act for the following types of short-term (three-months or less) research training:

There are several areas where judicious use of a three-month training period under the National Research Service Award Act without payback liability would be particularly advantageous for specific program objectives. These relate to research training of medical students and of students from minority groups.

Programs for medical students

Areas in which NIH makes postdoctoral institutional fellowship awards to train M.D.'s in research cover all program areas for which the Institutes are responsible. Anecdotal evidence from the field, as well as the experience of the various program managers, would indicate that recruitment of M.D.'s into these research areas is difficult. Since current medical school curricula do not offer opportunities for research in excellent laboratories, M.D. candidates are not exposed to the opportunities for clinical research at early decision-making points in their professional careers. Thus, most physicians choose other career opportunities and those who do elect to undertake postdoctoral training often are not well prepared to undertake research. A mechanism that would provide short-term opportunities to participate in ongoing research training programs may increase interest in research as well as provide an awareness of available opportunities.

At the outset, NIH Institutes would plan to invite applications from interested institutions that wish to provide well defined supervised training experiences for medical students on summer or "off quarter" periods.

Since these programs have already received peer review for suitability for post-M.D. research training, it is assumed that such training in the particular areas of research also is appropriate for highly selected medical students. It has been observed that some of the best trainers are postdoctoral fellows who would also provide role models for young medical students. It is anticipated that if such a research rotation were to be of such great interest to a medical student that he or she should wish to continue at other times during the subsequent school years, funds from research grants or other sources could be made available to support the continuing research experience.

Programs for minority students

The constituency served by the Minority Access to Research Careers Program would benefit by having access to a flexible mechanism for obtaining support for short-term periods of highly individualized training. Training programs would be designed to supplement and/or augment ongoing MARC activities by providing specific, intensified coursework, instruction, orientation or practical research experience for selected applicants from minority institutions. We would propose to develop training activities as follows: This program would require an announcement of such short-term institutional training program within the MARC Program. Applications would be invited to conform to guidelines which would broadly define the appropriate types of training as described above.

This would provide up to three months of support for a fixed number (2 per year) of highly qualified undergraduate students at minority institutions to (1) work in major research laboratories, (2) obtain intensified course work in the sciences not available at the home institutions or (3) obtain specific technological training. Such training is to be obtained in a majority institution, either close to or remote from the home institution or at a federal research installation (Argonne, Oak Ridge, etc.); the home institution should develop agreements with the training facility.

This also would provide up to three months of support for a fixed number (2 per year) of faculty members of minority institutions to obtain training in specific techniques, research tools or research areas (e.g., cell culture technique, isotope tracer techniques).

These are the two immediate major needs which would be fulfilled by use of the NRSA provision for exemption from the payback obligations of the Act for short-term training.

DOCTORS IN BIOMEDICAL RESEARCH

Senator EAGLETON. Could you meet sometime with the staff to go into it in greater detail?

Dr. FREDRICKSON. We would be pleased to do that, Senator. Actually, we must have some M.D.'s in biomedical research, or the translation of knowledge into practice simply will fail. We would be very glad to meet and discuss this critical and complex problem.

Senator EAGLETON. What is a typical salary of a research-oriented physician, his first year out, and what will that project out to in the next 5 years?

Dr. FREDRICKSON. Salary of a resident who has completed his specialty training is about $30,000. Our post-doctoral stipends are so low that a resident who has decided, to go into training for research would only receive about $14,500 per year.

We are so concerned about this that we must raise the stipend levels.

Senator EAGLETON. That self-evidently won't work, will it?

Dr. FREDRICKSON. The M.D.–Ph. D program is the single best hope for the training of researchers, because of the pace of science. You almost have to conduct research and medical training together.

So, it is crucial to train the M.D.–Ph. D.'s, and we are approaching this in several ways. We would be glad to share some of these ideas with you.

Senator EAGLETON. That $10,000 stipend, in order to up that, would it take additional authorizing legislation, or is there ample range in existing law?

Dr. FREDRICKSON. It will not require any authorizing legislation to increase the stipends. We can do that administratively.

Senator EAGLETON. I think this is very important. I'm going to ask the people here with us today to give some attention to this,

work us up a package, and let's see what the range of options might cost as to different concepts.

Take a guy who makes $15,000, and say, now, we know you are dedicated, we are going to give you heightened academic responsibilities, in terms of what you have to learn, but we are only going to pay you $10,000.

That just won't work.

We also want to take a look at the doctor's 3-month plan, and see what that is.

MINORITY ACCESS TO RESEARCH CAREERS

This minority access to research careers, tell me a little bit more about that, how long it has been going on, and how do you see it working?

Dr. KIRSCHSTEIN. This program has been in existence since 1972, as an informal program of the institute.

In 1976, realizing its great importance and expanding it, we made it a formal program of the institute, with its own program director.

It has three facets to it. One is the faculty fellowship program. In this area, we provide training for faculty members of minority institutions who leave those institutions for periods of up to 3 years to obtain training at an institution that can be considered to be a majority institution. These faculty members of minority institutions are of two types. Very often they are individuals with Ph. D. degrees, but in contrast to majority institutions, it is quite common for individuals to reach quite high professorial rank at minority institutions without an advanced degree.

Senator EAGLETON. This is more than Meharry and Howard.

Dr. KIRSCHSTEIN. We are talking about 128 primarily black colleges, and in addition some institutions that are considered eligible for such awards, because they have substantial numbers of Hispanic, American Indian, and Hawaiian populations.

So, some of the faculty fellowships are for the purpose of individuals who have reached assistant professor or associate professor rank at these colleges to leave those institutions and work on a Ph. D. degree, and get support for 3 years to obtain the Ph. D. degree.

Some offer people postdoctoral training if they have Ph. D. degrees, the idea being that at the end of that time, they will, and indeed all of them have, return to the home institution, and bring to that minority institution the benefit of the knowledge that they have gained. In addition, they will be able to stimulate research endeavors at those schools, so that perhaps the schools can begin to compete for research funds, as do many majority schools.

There have been 127 of such faculty fellows to date from schools all over the United States.

Senator EAGLETON. They have all gone back to their schools?

Dr. KIRSCHSTEIN. They have all gone back to their institutions.

Senator EAGLETON. We have a similar situation with the training of foreign medical students. The dilemma is, these men and women come over to be trained in the American medical system with the idea of going back to the Philippines, India, or Bangladesh. City

Hospital in St. Louis is totally staffed by—almost— foreign medical students who decide they want to stay.

Dr. KIRSCHSTEIN. These are not primarily medical school graduates. These are very dedicated people.

In addition, the second facet is the visiting scientist award in which distinguished scientists from majority institutions are given support to go to minority institutions to give to the students and faculty of those minority institutions their knowledge and wisdom and help them with their research programs. This program has been a little less successful than the other one, in the sense that it is very difficult to persuade such individuals to go away from their home institution for a long period of time. And over the years we have made a change such that visiting scientists can go to minority institutions for 3 months, or 6 months rather than a year.

In addition, this program has to be implemented under the National Research Service Act, and in the past was hampered by the stipends that we could pay, because of the law in that regard.

There was, as you may know, special legislation for this program, and now we can pay these distinguished scientists from majority institutions the salaries that they could get at their home institutions when they go to minority institutions.

STIPENDS

Senator EAGLETON. So the stipend for the professor going from the majority institution to the minority institution, is basically the same salary as he or she was getting?

Dr. KIRSCHSTEIN. Yes.

Senator EAGLETON. What is the stipend of the other?

Dr. KIRSCHSTEIN. The stipend for a person who is working on his Ph. D. degree would have been very low, as are all predoctoral stipends, $3,900; this would be impossible.

There has also been legislation allowing a stipend of up to $25,000. So that we have been able to help these individuals.

Senator EAGLETON. Do some in fact get as much as $25,000?

Dr. KIRSCHSTEIN. Yes.

Senator EAGLETON. If a fellow has a wife and five kids, does he get a bigger stipend?

Dr. KIRSCHSTEIN. No. It is dependent on the salary that he has at his home institution.

MARC HONORS UNDERGRADUATE PROGRAM

The third part of the program is the one that is the newest, and is a pilot program. This is the honors undergraduate program.

What we feel is needed, in order to really begin to have an impact on the number of minority scientists, is to begin to interest individuals at minority schools in research careers much earlier than after they have finished college. So what we are doing is giving training grant awards to the minority institutions to support undergraduate students in their junior and senior year at school, with the idea that special curricula will help them learn research and will develop a good scientific base to enable such students to compete well and become graduate students at majority institutions.

That program has been in existence since September 1977. The first class of students graduated last June. There were 24; and of those 24, 12 have entered graduate school in biomedical sciences.

Senator EAGLETON. I just sort of gather by the way this is phrased, you are not as pleased as to how this program is working as the other two?

Dr. KIRSCHSTEIN. Not at all. It is only a year and a half old, so we really do not know. We feel it is a pilot program, and as such, we hope to continue to evaluate it.

We feel that it is a very worthwhile program. The initial number of applications received was 69, of which 29 were approved, and 12 were funded with the earmarked funds that came out of this committee for that year.

We have added five more awards since then, so there are a total of 17 now.

5-PERCENT REDUCTION

Senator EAGLETON. Senator Magnuson in yesterday's hearing with several Institutes, asked each of the directors of those Institutes what would they do if they were cut 5 percent?

I've got a similar line of questioning. I have the agriculture budget, and I've asked the Agriculture Department to give me their lowest 10 percent priorities, so we are starting with zero. I'm threatening them with a 10-percent cut. I just want to get their pecking orders of reverse priorities, so to speak.

So, I think since Chairman Magnuson started that line of inquiry, we ought to continue doing that.

Did you want to give me a little gist of what your bottom 5 percent is, or would you prefer to think about it and give it to us in writing?

Dr. KIRSCHSTEIN. I will supply this for the record in writing.

[NOTE: This insert was provided as a part of the NIH Overview.]

Dr. KIRSCHSTEIN. As my opening statement indicated, as the basic science institute, we feel that what we need to protect most are investigator initiated research grants, and particularly, in programs such as basic studies in genetics, and cellular biology, molecular biology, and basic pharmacology.

So, we would have to do some thinking about how we would cut some of these other areas. But in general, those are the areas that we would like to protect.

Senator EAGLETON. Think it out, and give us something in writing.

QUESTIONS SUBMITTED FOR RESPONSES

[The following questions were not asked at the hearing, but were submitted to the Department for response subsequent to the hearing:]

BURN RESEARCH

Question: How has your cooperative program with Health Services Administration and Emergency Medical Services program fared in the area of Burn Research?

Answer: While it is the mission of the Health Services Administration (HSA) to support initiatives in the delivery of better emergency medical service, and thus to translate research findings into patient care, the National Institute of General Medical Sciences (NIGMS) makes every effort to cooperate with HSA, within the limits of its research mission. As part of its mission, the NIGMS supports research and research training programs related to the pathobiology of trauma and burn injury. These programs involve the study of the body's total response, and the biochemical and physiological changes induced by trauma, as well as the fundamental aspects of wound healing and biological repair.

Research on the treatment of post-traumatic infections, the nutritional requirements of convalescing patients, and the rehabilitation of injured patients is also supported.

The NIGMS-supported burn and trauma research centers provide a multidisciplinary approach in which new knowledge gained in the laboratory can be utilized in patient care.

Four of these research center grants are directly coordinated with the Emergency Medical Service trauma programs, which are located in the same cities. Two directors of large NIGMS-supported research grants were awarded contracts by HSA for burn demonstration programs to gather data on regional burn care systems. These activities permit rapid transfer of research findings to the care of patients.

In addition, the Institute staff works closely with the EMS Program staff and keeps that agency informed of our research activities. In FY 1978, NIGMS staff members assisted in the review of contract applications for the burn demonstration program of the Division of Emergency Medical Services.

Question: Two years ago, there was quite a bit of interest and support in the area of public education programs regarding burn treatment. Frankly, we have not heard much about this in the past year and a half and are wondering what you are doing and whether or not you still consider this to be a priority item.

Answer: The NIGMS continues to be active in the transfer of knowledge related to burn injuries to the community of practicing medical professionals and the public.

In FY 1978 the Institute used the Communications Technology Satellite (CTS) to disseminate health research findings in burn care to lay people, primary care physicians, and paramedical practitioners. The CTS linked Fairbanks, Alaska (where the death rate from burns is higher than from any other cause), to Seattle, Washington (in which there is a burn research center), to Bethesda, Maryland. Three burn specialists, Drs. P. William Curreri, John F. Burke, and Charles R. Baxter in Bethesda discussed case presentations made in Seattle. Question and answer sessions took place between the three locations.

This satellite discussion was condensed into a 30-minute film on the state-of-the-art of burn care.

In FY 1979, the Institute sponsored a consensus development conference on Supportive Therapy in Burn Care. In attendance were burn specialists, nurses, paramedics, representatives from 10 Federal agencies, members of the public from 33 states and 7 foreign countries, and members of the press. Consensus was reached on a number of critical issues, including the amount and type of fluid resuscitation required following burn injury, the use of steroids in the treatment of smoke inhalation, the use of antibiotics to curb infections, and nutritional support following burn injuries.

Both technical and lay summaries were prepared immediately following the Conference and were disseminated to the press and other media. The full proceedings will be published in the Journal of Trauma. In conjunction with the Conference, an issue of the News and Features from NIH was devoted to burn research.

GENETIC COUNSELING

Question: Genetic research is getting more and more support and visibility as a means of establishing a link for future counseling programs. This would be a way to head off disease before it even takes place in humans. We have now funded the Genetic Information and Counseling Program in the Health Services Administration and I'm wondering if you can give us some specifics as to how you inter-relate with this program.

Answer: The Genetic Information and Counseling Program of the Health Services Administration (HSA) was set up and funded as part of the implementation of the National Genetic Diseases Act (PL 94-278), which was renewed in 1978. The Public Health Service Genetics Coordinating Committee was established to assure coordination of the National Institutes of Health (NIH) programs of research on genetic diseases and the HSA programs offering services, such as provision of information and counseling. The National Institute of General Medical Sciences (NIGMS) is the lead NIH Institute in this coordinated effort, and the Director, NIGMS, regularly meets with and advises the staff of HSA charged with implementation of the services program.

A public meeting related to implementation of the Genetic Diseases Act was organized by the Director, NIGMS, together with the Coordinating Committee, and was held in December 1977. The report of that meeting emphasized the need for better public education related to genetic diseases. As a result, the HSA awarded a contract for the establishment of a National Clearinghouse for Human Genetic Diseases. Since the staff of the NIGMS Genetics Program has, for many years, responded to a large number of queries about genetic diseases from the general public, and also has developed several brochures on the relationship of genetics to human health, the Clearinghouse sought and obtained advice from NIGMS about a number of aspects of the development of a national informational program on genetic diseases.

NIGMS will continue to cooperate with the Health Services Administration and the Clearinghouse whenever the Institute's interest in and support for genetics research can be helpful to their efforts.

Question: Do you feel that the increased emphasis being placed on genetic research and genetic counseling is a good place to be putting our limited resources?

Answer: Diseases involving disorders of the hereditary material--the genes and chromosomes--are the most widespread and probably the most burdensome of all human afflictions. About six percent of the population suffer from some form of severe genetic disease; and the cost, both to society and to individual families, is enormous. For example, the cost to society of caring for those suffering from Down's Syndrome is estimated to be about $1 billion each year.

I feel quite strongly, therefore, that work in this area should be supported and emphasized, despite any limitation of resources. Genetics research is necessary for a better understanding of the causes of and mechanisms underlying the development of genetic diseases. The genetic counseling which can result from such an understanding may lead, in turn, to the prevention of disease, and is thus cost-effective.

PRIORITIES

Question: Given tight fiscal constraints, Dr. Kirschstein, where would you place your highest priorities in terms of the programs within your Institute?

Answer: The program areas of highest priority within NIGMS are those that relate to basic biomedical research in genetics, cell biology, molecular biology and molecular pharmacology. Research progress in these four areas is the essential undergirding for all the activities related to the various diseases and the specific population groups represented by the other Institutes of NIH.

Question: How much money does this take in terms of what is being requested in your fiscal year 1980 budget?

Answer: The grant funds requested for these program areas in the President's F.Y. 1980 budget total roughly $170 million.

HIGHLIGHTS

Question: Dr. Kirschstein, in your opinion, what are the most significant contributions your Institute has made to biomedical research and health care in this country in the last five years?

Answer: Investigators supported by the National Institute of General Medical Sciences (NIGMS) have made a large number of significant contributions to biomedical research over the last five years, all of which have implications for health care. I would select the following as, perhaps, the most significant:

The Production of Medically Useful Proteins (such as human insulin or growth hormone) Using Recombinant DNA Technology

By inserting the genes for portions of the human insulin molecule into plasmids in E. coli bacteria, scientists supported by the NIGMS Genetics Program have been able to make the growing bacteria produce

the two precursor chains of human insulin. These two chains can be joined synthetically, thus producing active human insulin, a substance of great importance to the treatment of diabetes. Commercial pharmaceutical manufacturers are now attempting to produce human insulin on a large scale using this methodology.

NIGMS has also supported studies which have led to the successful insertion of a gene of a rat into bacteria to produce the complex hormone that regulates growth. Successful production of the rat hormone means that the use of similar recombinant DNA techniques may provide, for the first time, a plentiful source of human growth hormone, a rare substance used to treat dwarfism in children.

The Elucidation of the Basic Biochemical Defect Causing an Increased Cholesterol Level in the Blood

High blood cholesterol levels can play an important part in the development of coronary artery disease and heart attacks. In a genetic disease called "familial hypercholesterolemia," in which heart attacks occur at a very young age, a basic biochemical defect on the surface of cells has been demonstrated.

Normal cells have a surface or membrane receptor which binds proteins containing cholesterol. This, in turn, stops the synthesis within the cell of an enzyme which stimulates the cell's own production of cholesterol. Scientists supported by the NIGMS Genetics Program have shown that, in familial hypercholesterolemia, the membrane receptor for cholesterol is lacking and the negative feedback which stops the production of the cholesterol-synthesizing enzyme does not occur, leading to excess production and accumulation of cholesterol and thus to heart attacks. This knowledge may one day be used to prevent early deaths.

Assembly of Ribosomes

Ribosomes are microscopic, highly complex components of all cells. They are the factories in which all proteins are synthesized. To accomplish this function, ribosomes bind together all the ingredients necessary for protein synthesis, including (1) the "blueprint," derived from the nuclear genetic material (DNA), (2) the amino acids, which are the "building blocks," and (3) the energy required to put the amino acids together in the sequence prescribed ultimately by the DNA.

In order to accomplish this task, the ribosome is necessarily made up of many parts, including both proteins and nucleic acids. As with any other machine, it must be taken apart and put together again before its function can be truly understood. An NIGMS grantee, Dr. M. Nomura, of the University of Wisconsin, was able to dissect and reconstitute ribosomes, thus contributing substantially to our understanding of how they function. His work is an example of how diverse scientific thrusts involving, in this case, protein biochemistry, nucleic acid biochemistry, and both analytical and synthetic methodology, come together in a significant advance.

The findings of Dr. Nomura may one day make it possible to reproduce, in the laboratory, all the assembly events that occur in living organisms for the production of proteins. The achievement of

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such a complete system would represent a necessary step toward comprehensive understanding of the biogenesis of organelles (cell organs), and eventually, of the more complex behavior and genesis of cells.

The Elucidation of the Role of Hormone-Like Materials Called "Prostaglandins" in the Physiologic Processes of Disease

The discovery of a new prostaglandin or hormone-like material, called "thromboxane," has led to studies by grantees of the NIGMS Pharmacology-Toxicology Program on its release from platelets. Platelets are components of the blood which aid in clotting and which aggregate when the lining of an arterial blood vessel is injured. As the platelets aggregate, they release thromboxane, causing the wall of the artery to constrict, reducing blood flow and, thus, the oxygen supply to the tissue the artery feeds. This may lead to a heart attack or a stroke. If a chemical which can counteract thromboxane can be found, such events may well be prevented.

The "Processing" of Proteins Produced by and Secreted by Cells

The "signal hypothesis," developed by grantees of the NIGMS Cellular and Molecular Basis of Disease Program, has provided information of great importance about the processing of cellular proteins produced for export to other cells. According to their findings, the cell produces a precursor protein which has an extra portion on it. This segment acts as a "signal" by attaching itself to specific receptor molecules on the membranes which line the tube-shaped channels within the cell. The protein to be exported is thus guided through the walls of these channels, the "signal" segment is clipped off, and the functional protein is released for transport to other cells where it is needed.

Among the proteins produced for export to other cells are those involved in glandular secretions. There are numerous malfunctions of the secretory mechanisms; and many, such as that which occurs in cystic fibrosis, are of unknown etiology. A more complete understanding of the biochemistry of secretion will allow researchers to trace the causes of many common diseases, and serve to help in the development of effective treatment and techniques of prevention.

RESEARCH PRINCIPLES

Senator EAGLETON. NIH recently held a conference trying to establish goals and recommendations for the next 5 years as far as biomedical research is concerned.

Do you have any specific program changes planned in response to this proposal to look at the biomedical research programs more closely?

Dr. FREDRICKSON. Would you like me to answer that?

Senator EAGLETON. Yes.

Dr. FREDRICKSON. We are on the road toward developing a new set of research principles, or rearticulating the underlying philosophies of maintaining the health science establishment.

We've had a lot of assistance from the general community. Dr. Danforth from St. Louis was extraordinarily helpful. He headed our fourth panel on the requirements to sustain the capability, of the system.

Senator EAGLETON. Although he doesn't want this advertised, Dr. Danforth supported me for the Senate. He's a great man.

Dr. FREDRICKSON. We think so, too; he was really extraordinarily effective in contributing to this exercise.

What we are hoping to do, Senator Eagleton, is to come up with a general consensus of a large community of interests. At some time we want the Congress, too, to participate in this, to see if we can all come to agreement about our goals, how to maintain an attractive, reasonably stabilized system for scientific inquiry, as represented by this biomedical research organization, the NIH, and the constituency that it has; how to make sure that we effectively couple the science base, basic research, and applications; how to make the priority selections, and where to put our emphasis; and what does the system need, how do we get the M.D.'s, and how do we keep them; what are the problems of attracting people into the system; and what does the system need to sustain it, both the instruments and the physical plant, as well as the human capital.

The Institute of Medicine of the National Academy of sciences was asked to prepare an independent report of the conference. That report is just finished, and I hope to see it this weekend, and to talk to the institute group on Monday.

All of the health agencies in the PHS are now looking at the health principles as they have been developed.

We are evolving a common base for analyzing all the activities in the health agencies, and we hope by next fall that we can come up with a reasonable set of strategies, which we might share with the rest of the administration and with the Congress to see if we can achieve some of these long-range goals.

I think that one of the most difficult jobs is undergerding the maintenance of a system that clearly must go on for the rest of our lives, and long beyond that, and must maintain its capability of attracting the best minds, and to meet the total health needs of the Nation, which all depend upon knowledge in one way or another.

We are sensitive to needs of the regulators and people with other missions. How can we meet the needs and relate them to the technical opportunities for research? We are still on the way, attempting to do this in a conscientious and effective way. I think we have a chance to do something useful.

COLLABORATION WITH OTHER COUNTRIES

Senator EAGLETON. Going through this important introspection, are we learning any lessons from other countries? I don't know whether it is Britain, Germany, Japan, Belgium, or France. I'm not talking about specific cures and breakthroughs; but in terms of the 5-year overview, where we are heading, where we are going? Is there anything you can borrow from abroad?

Dr. FREDRICKSON. Really the obverse is true. In April we will meet with the heads of all the medical research councils in Europe here in Washington, and we will discuss this very problem to see what they might contribute to it.

Last year I was in London, and I was interested to note that we all have the same concerns: how to deal with the needs for application, for regulation; how to couple health services research to basic

biomedical research. England has tried certain plans, and we should be able to learn something from them. We are in the vanguard of the attempt to come to grips with a set of problems that really are quite universal. Every country that is trying to cope with increasing health care costs has exactly the same question: How do you bring knowledge to bear on this extremely important, difficult, complex problem?

Senator EAGLETON. By the way, I went with Senator Ribicoff to the Soviet Union, and we had a lot of days of debates and exchanges on a long table such as this. One night we were all invited out by one of the Russian colleagues. Mine was Dr. Fredrickson of the Soviet Union.

Help me with his name.

Dr. FREDRICKSON. Vendicto?

Senator EAGLETON. His daughter is studying to be a doctor, and he's about 60 years of age. He's as somber as Kosygin is ebullient.

Dr. FREDRICKSON. I believe you mean Nicholai Vicholaiovich Blokhin; I know him very well. He is president of the Soviet Academy of Medical Sciences.

Senator EAGLETON. We were all invited to each sponsor's home.

Dr. FREDRICKSON. Did you see his paintings?

Senator EAGLETON. Yes.

Dr. FREDRICKSON. Did you drink vodka with him?

Senator EAGLETON. We toasted everything.

Do all you doctors do that?

Dr. FREDRICKSON. That is part of our training.

Senator EAGLETON. Thank you.

National Institute on Aging

STATEMENT OF ROBERT N. BUTLER, DIRECTOR

ACCOMPANIED BY:

DONALD S. FREDRICKSON, DIRECTOR, NATIONAL INSTITUTES OF HEALTH

NORMAN D. MANSFIELD, DIRECTOR, DIVISION OF FINANCIAL MANAGEMENT, NATIONAL INSTITUTES OF HEALTH

ROBERT L. RINGLER, DEPUTY DIRECTOR, NATIONAL INSTITUTE ON AGING

KENNETH S. LEVINE, DEPUTY ASSISTANT SECRETARY FOR LEGISLATION

WILFORD J. FORBUSH, DEPUTY ASSISTANT SECRETARY, BUDGET

BUDGET REQUEST AND PREPARED STATEMENT

Senator Eagleton. The Aging Institute. $56.5 million requested. Dr. Butler.

Dr. Butler. I will submit my prepared statement for the record, and comment at this time on only a few of its highlights.

[The statement follows:]

STATEMENT OF ROBERT N. BUTLER

Mr. Chairman and Members of the Committee:

It is an honor to appear before you, to report our recent progress in aging research, and to present the budget request for 1980.

Three themes run through my remarks today: what we are doing to facilitate transfer of geriatric knowledge to health care professionals; a description of some of the health problems of the elderly; and the relationship between these problems and promising research we are currently supporting. Throughout these remarks I will describe several cooperative endeavors under development.

In spite of the publicity given to the demographic data on age changes in our society, it is important to reemphasize certain facts about the elderly and their health. A higher standard of living; reduction in infant, childhood and maternal mortality; and other advances in medicine and public health are causing a rapid increase in the number of people over 65. Eleven percent of our population, or 23 million, have attained the age of 65. This figure increases by 1,400 each day or 500,000 each year, a rate that will increase. This phenomena is, in my view, a most significant triumph for mankind. Nevertheless, it creates problems that we will need to address.

A major concern of mine has been the development of our capacity for high quality clinical research and the transfer of knowledge on the problems and needs of the elderly to doctors and other health professionals. We have several activities underway in this area. Recently we announced a geriatric medicine academic award program and have received a very encouraging response. A primary objective is the development of a superior faculty in geriatrics within our medical schools and schools of osteopathy. In addition to this program, the Institute and the Health Resources Administration are working together on programs to encourage curriculum development in geriatrics in all health profession schools.

Another way to disseminate knowledge about geriatrics is technical consensus development. For example, the symptoms characteristic of what is popularly called "senility" include serious forgetfulness, disorientation, intellectual confusion and certain other medical and emotional disturbances. These symptoms are not an inevitable consequence of age, although doctors and patients alike have accepted them as such. To draw the attention of physicians to the danger of accepting the stereotype of the old as senile, the Institute and the Fogarty International Center brought together experts in a variety of medical fields for a consensus development conference on treatable brain disease in the elderly. This conference will result in a summary consensus document that will be distributed to health care practitioners.

Physicians and researchers can learn much from distinguished geriatricians in other countries. Thus, the Institute is working with the Fogarty International Center to support Senior International Fellowships in Aging. These fellowships help senior U.S. investigators travel abroad to study and share their own expertise with gerontologists in host countries. The Fogarty Center expects to make the first awards under this program this year.

One of the characteristics of our elderly population is its diversity. The majority are vigorous and independent. Others are often frail and dependent on someone else to provide for their physical well-being. Furthermore this diversity is increasing. In 1950, about one-

third of our elderly were over 75; in 1980, 38 percent will be over 75 and by the year 2000, 45 percent will be over 75. These trends deserve our attention since, at present, the older a person becomes, the more likely the need for expensive medical care. For example, 7% of the men over 75 were institutionalized as are 10% of the women.

It is fortunate for many reasons that most elderly Americans can and do remain in their own homes. This Institute seeks to enhance even further the independence of the elderly by reducing the need for institutionalization. For example, improved or new prosthetic devices may allow the elderly to regain mobility, or improve vision, hearing or manual dexterity. This year the Institute signed an agreement with the National Aeronautics and Space Administration to support projects that would apply space technology to the needs of the elderly.

A major factor in the need for special care of physical or mental disabilities in the elderly is also the most fearsome: mental decline with age. The exact incidence of senility is unknown, but it has been estimated that up to fifty percent of the nation's nearly one million elderly in long-term care institutions become institutionalized because they have been diagnosed as "senile." This area has become a major emphasis of the Institute. During 1979 our neuroscience laboratory at the Gerontology Research Center in Baltimore became fully operational. The extramural research program has increased the number of grants on organic brain disease and other studies of age-related change in the central nervous system. Our epidemiology, demography and biometry program is initiating a study on senile dementia in an elderly population under investigation by the National Institute of Mental Health.

There are a number of leads to pursue in the neuroscience area. Recent research indicates that age-related changes in the central nervous system may be caused by breakdown of the blood brain barrier, which restricts exchange of water-soluble drugs and proteins between the blood and the brain. If the blood brain barrier does not function properly, the brain will not get elements it needs in the right quantities. Also, recent investigations have shown a way to temporarily increase the permeability of the blood brain barrier so that certain drugs can cross this barrier, allowing for treatments not otherwise possible. Another line of research seeks information on the relationship between aluminum and the deterioration of the nerve endings in the outer layer of the brain characteristic of Alzheimer's disease. Aluminum may interact with DNA (a substance carrying primary genetic information) and this interaction may result in the lesions characteristic of Alzheimer's disease. Further research is needed to determine if this interaction occurs and how it might be blocked.

The potential cost savings to the economy of advancements in this area are enormous. If we could prevent 100,000 nursing home admissions the savings to the economy could amount to 1.5 billion dollars annually. Therefore, the Institute is actively planning joint research programs with the National Institute of Mental Health and the National Institute of Neurological and Communicative Disorders and Stroke to bring the latest technology and expert knowledge to bear on these problems.

Nutrition is another area of particular interest to our Institute. Deficiencies and excesses in nutrients such as vitamins and minerals, and their interactions with drugs, for example, are known to be associated with nervous system disturbances, to influence wound healing, and to affect a number of other processes. Because our understanding of these associations is presently primitive, we are pursuing several lines of investigation. Recent research shows that restriction of calories affects the number of fat cells in the body at any point in adult and later life, improves response to certain hormones which remove fat from

fat cells, and helps maintain muscle function. Further research will explore whether caloric restriction has an effect on other important functions such as the degeneration of bones and malfunctions of the liver.

The Institute recently joined the National Cancer Institute and the National Institute of Arthritis, Metabolism and Digestive Diseases in a request for applications for clinical nutrition research centers. These centers will strengthen multidisciplinary research in order to develop new knowledge about the role of certain nutrients in health, human development, and the prevention of disease. Activities supported by these centers will complement individual project grants by providing facilities and services beyond the reach of the individual investigator.

The Institute is also investigating differences in life expectancy between the sexes and among races and ethnic groups. Currently there are 146 women for each 100 men over 65. Even more striking is the fact that, for the over 75 population, there are 176 women for every 100 men. Variations by race and ethnic origin also exist. The proportion of whites over 65 is 11%; of blacks, 8%; and of Spanish-surnamed, 4%. To identify these differences, a model has been developed that relates age, race and sex to deaths from five chronic diseases: heart disease, stroke, arteriosclerosis, hypertension and cancer. Already the model has demonstrated consistent race differences in circulatory diseases. An early increase in black mortality appears, for example, to be related to a lower resistance of blacks to circulatory problems and risks. In addition, the model has delineated the "cross over" phenomena in which blacks shift, at about age 75, from a disadvantage to an advantage over whites in terms of life expectancy.

A crucial role for this Institute is to provide a solid research data base for public policy decisions on the economic costs of the elderly that have been so widely discussed as a major limiting factor in the flexibility available in the federal budget. Retirement stands out as one of these major public policy issues. The requirements of the social security trust funds and pension plans are often viewed as major burdens that society must bear in ever increasing quantities. Yet, what if people worked longer or remained healthier during their retirement years? Wouldn't these burdens be eased somewhat?

The Institute has a responsibility to provide the data for discussion of intelligent public policy alternatives that will be considered in the years to come. To carry out this function, the Institute has encouraged the submission of grant applications to begin developing the knowledge base that is required in public policy discussions of retirement. Envisioned are studies of the elements involved in the retirement decision; the impact of retirement on health; the development of functional performance indices of aging to assist in flexible retirement assessments; and factors involved in successful or unsuccessful adjustment to retirement. The first awards in response to this announcement will be made this fiscal year.

The triumph of the increasing number of elderly creates a continuing challenge for the research community to assess and to meet the health needs of the elderly. The research programs of the National Institute on Aging are beginning to meet this challenge. Mr. Chairman, the 1980 budget request for the National Institute on Aging is $56,510,000.

Dr. BUTLER. As you know, about 57 cents out of every Federal dollar is devoted to aging. We can meet the challenge this development presents in several ways. The first is to find, perfect and introduce better and more effective means of health care through improved basic knowledge regarding diagnosis.

Second, to build upon the new field of geriatrics, and further develop our knowledge in the basic scientific fields such as biology, neurosciences, pharmacology and nutrition. And third, to do this with some very real concern about the containment of cost.

Related to this latter point, for example, is the prevalence of senile brain disease, which probably accounts for about 50 percent of the people that are in nursing homes.

Senator EAGLETON. I'm sorry? What?

Dr. BUTLER. I was saying that the point I made was that we must always be conscious of the tremendous costs of these health problems on the elderly, and to devote our energy to these problems, and thereby prevent the institutionalization of many of these individuals.

Today there are more people in nursing homes than in hospitals. There are about 1 million people over 65 who are in nursing homes. Perhaps half of those suffer from senile dementia, popularly referred to as senility.

They may have other diseases. But perhaps the main reason they are in the nursing home is they no longer have the capacity for self care as a result of the terrible encroachments of senile brain disease.

So those are among our major objectives, and, of course, our development as a new Institute requires us to face some very real problems in an imaginative way.

DEMOGRAPHIC TRENDS AND NIA GOALS

I also want to bring to the attention of the committee, the realities of the demographic trends of the nation.

What these reflect, of course, are the contributions of the various NIH institutes represented here today; namely, the contributions that have led to reductions in infant and childhood mortality, and other advances in medical health, that have allowed more individuals to attain the age of 65 years.

These changes must be of real interest to all of us as American families face the burdens of rising health costs, multiple disease states which often result in physical dependency and institutionalization. The burden of all this is on the American family which continues to be the number one caretaker of older people.

Our goals then are clearly not to perpetuate the lives of the dependent, disabled and sick but rather to find ways to extend the healthy, productive, vital middle years of life into old age.

But to do this, we must work toward the provision of adequate resources to take full advantage of the imaginative efforts of American scientists, to create centers of excellence, to develop attitudes in the nation's medical schools so that the interest of pharmacologists, biochemists, epidemiologists, and those in the clinical science departments in the field of aging is enhanced.

Almost all of our budget is developed to support basic science, to the augmentation of the science base, and to the understanding of the fundamental biological processes of aging, the understanding and perhaps control of which could provide a means for delaying the onset of various diseases.

Aging is defined in many ways, but among them is that it is an increasing vulnerability over time, ending in death. The control of the rate of the occurrence of that vulnerability; that is, of aging, could have remarkable implications in terms of delaying the onset and reducing the severity of diseases, and at the same time reduce their costs.

As one example, in many respects the understanding of cancer and aging both depend upon basic cell biology, the molecular biology research that Dr. Kirschstein earlier described so appropriately.

We must, of course, address a variety of time-dependent changes on the central nervous system, such as the reduction of the speed of reaction of the response, the immune system that declines with age, and hormonal changes that occur with age.

Another change is how the body modifies its handling of drugs and nutriments as people grow older. None of this can be accomplished without some real indications to the larger communities, including the medical community, of how this research can contribute to the improvement of the everyday lives of older people.

All of this has led the Institute to the development of the geriatric medicine academic award, which is designed to create an atmosphere of interest within medical schools toward the development of research proposals in aging. I'm pleased to respond that of the 120 medical schools in the United States, some 43 have already indicated a definitive interest in curricula development and faculty development in medical schools in the field of geriatric medicine.

We have already reviewed some 23 proposals that have been received to date and are hopeful that this year about 10 or 15 percent of our medical schools will receive such awards. But this would be an extremely important beginning, and would represent 10 to 15 percent more than we've ever had before.

GERIATRIC MEDICINE

Senator EAGLETON. How many medical schools in the country have a chair in geriatric medicine, whether endowed or unendowed?

Dr. BUTLER. At the moment, there is only one official endowed chair of geriatric medicine, and that is at Cornell University.

In addition the State of Ohio has required its seven medical schools to develop divisions, or units of gerontology.

These programs are beginning to spring up in a variety of medical schools in the country. It has been really quite heartening to see the extent to which the medical schools have become interested in this problem.

The medical professors, the Institute of Medicine, and the Association of American Medical Colleges, are increasingly responsive. In fact, one of the most effective ways to reach medical students and teachers is to introduce changes to the boards of internal medicine

examination questions. I was called recently by Dr. Benson, the president of the Foundation for the Board of Internal Medicine for just that, the incorporation of questions regarding geriatrics on the examination given to the medical students. The significance of this action is that the teachers will teach the subject matter, and students will study it, if they know the questions are going to be in the examination.

So we do see some significant and positive changes in the medical schools.

Senator EAGLETON. What will this mean in dollars? Will you give them enough money, not to endow a chair, but to pay half the salary of a professor of geriatric medicine?

How is that going to work?

Dr. BUTLER. In fact, it is very modest and time-limited. We do not want this to be something that goes on for a long period of time. We expect the faculty and the dean of the medical school to be very supportive of the development of the curriculums and faculty change.

Senator EAGLETON. How many dollars? What does the award amount to?

Dr. BUTLER. We have asked the schools to come up with their own programs with some guidance from us, but it looks like they are in the range of $50,000 or $60,000 per award.

Senator EAGLETON. That would be $50,000 or $60,000 for 1 year?

Dr. BUTLER. Yes, for 1 year and for no more than 5 years. Per year, for a 5-year period.

They know that in advance.

Senator EAGLETON. They know that in the beginning. It's sort of a pilot program. The hope is that they will carry it on. But as you know, sometimes in these pilot programs, they say, well, we just don't have the wherewithal to do it, will you give us another 5 years?

Dr. BUTLER. It is a new program, so, of course, we have to be thoughtful in developing the policies.

We are interested in the seriousness in which commitments are made, and we suggest a contribution from the medical school itself that will go beyond the 5 years of NIA sponsored activity. We also recognize the need for different schools to develop different approaches, depending on the character of the individual institutions.

MEDICAL SCHOOL TRAINING

Most schools in the United States do not require medical students to rotate through a nursing home, even though as I mentioned, we have more patients in nursing homes than we do in hospitals.

I don't know of any program in which you have a health promotion and disease prevention clinic for older adults and therefore most medical students only see the sick elderly. If a medical student never saw a well youngster, but instead saw only those who had cerebral palsy, or serious malignant disease, how many would go into pediatrics?

There should be means for providing the student with a range of opportunities with respect to the positive characteristics of older people, as well as their disease states.

Senator EAGLETON. Any student or intern or resident would see a lot of elderly in any typical teaching hospital, would he not?

Dr. BUTLER. That's right, but the quality with which that experience reveals itself can be quite valuable. For instance, sometimes the older patient in a chronic disease hospital is treated as a medical museum which reveals to a variety of different diagnostic signs, and not for teaching recuperative abilities and restitution in the face of a variety of illinesses.

It is not a positive presentation of the older patient to the medical student.

But we are anxious to give the medical schools some opportunities to become comprehensive in the way in which they develop programs in geriatric medicine. We plan to have them come together at NIA at least once a year so that they can compare notes, learn from each other, create curriculum models, and discuss mechanisms for stimulating research in medical students. We are very hopeful that it will be the medical student stipend-type of program that Dr. Kirschstein mentioned earlier. Clearly, with the very real and unique aspects of the older person, we need to have a new type of study.

MULTIPLE DISEASES IN THE ELDERLY

The average person age 65 or older has five diseases at the same time, and is on an average of eight medications at one time.

Senator EAGLETON. People over 65?

Dr. BUTLER. This is an aggregate statistical figure. It doesn't mean that it applies to any one individual. Such occurrences make it an extraordinarily interesting pursuit, to be able to look at people as they grow older, to observe the changes in thermoregulatory capacities, declining immune system, the different ways of handling medications.

Dr. Kirschstein, of the General Medical Sciences Institute, and our Institute have collaborated in the area of pharmacology and aging, for example, and have created a very useful and instructive beginning toward stimulating American pharmacologists in addressing such a fundamental matter as how, when we grow older, we change in the absorption, distribution, metabolism, and excretion of drugs.

We know very little about this subject. Yet, drug interactions are obviously going to be quite frequent when the older person is on an average of eight medications.

We clearly have a long way to go.

Senator EAGLETON. To put it in laymen's language, if a 25-year-old were on three or four medications, that person's ability to absorb them all without one conflicting with the other might be very much different than a 70-year-old person on the same three or four drugs?

Dr. BUTLER. That is correct. And, of course, it is not likely that the younger person would be chronically on as many medications as an older patient. And the older patient may make certain mis-

takes without adequate assistance and information regarding special provisions for taking the medications, without, for example, appropriate package inserts to assist the patient in knowing the types of drugs which may interact. Unfortunately, however, there are a great many that interact that we don't know about. One classic example is the excessive bleeding which may occur when someone is on both aspirin and warfarin, which is an anticoagulant.

One also sees paradoxical responses.

VITAMINS AND DRUGS

Senator EAGLETON. What about vitamins? I have an aunt who is a vitamin freak.

Has any research been done on taking medications plus vitamins?

Dr. BUTLER. One very simple example from clinical experience is the extent to which mineral oil can drain out certain vitamins, including vitamin K. Also, the postmenopausal woman may deactivate vitamin K.

This is an important fact. One of our grantees this year found that vitamin K, which is usually thought of as playing a role in coagulation and the maintenance of osteocalcium, a protein in bone, leading to a depletion of calcium, may bear some relationship to osteoporosis. And it could well be that simply taking mineral oil at the same time that one is eating natural foodstuffs, which are actually quite replete with vitamin K, may have a negative effect. So there are even nutrient-medication interactions in addition to medication, medication interactions. And there are paradoxical ones. If you give certain sedatives to older people, they can surprisingly have an agitating effect.

We are trying, of course, to bring together what we do know in consensus-type exercises, which we described earlier today.

Senator EAGLETON. What about sleeping medications?

Dr. BUTLER. Yes. Barbiturates are among that class of drugs which, given to an older person, particularly in the presence of brain damage, may lead to a severe agitative state. Unless the physician is conscious of this, or the family is fully aware of it, quite disastrous results can occur.

CONSENSUS DEVELOPMENT

This does bear on another point I might make. We must not only, of course, address the fundamental need for new knowledge, but we must bring together and make available the best informed opinion of what we already know, or think we know, or hope we know.

We have at the Institute created a consensus effort in treatment possibilities in brain disease. What this means, in short, is that many people have been written off as having senility when in fact it was a reversible condition, but only reversible if the underlying basis for that senility was recognized, properly diagnosed, and properly treated in a timely fashion.

As we grow older, we often don't show signs and symptoms in the same way as younger people. That is again one of the reasons

why we have needed to be attentive in developing a knowledge base of geriatric medicine. So without this knowledge, telltale signs may not be known to the physician. So we are developing a document which we hope will soon be very widely published, first to the practicing community, and then to the public at large, with respect to the treatment possibilities of senility.

Similarly, we have been interested in the appropriate indications and guidelines for the administration of estrogens in postmenopausal women. We will be having a major consensus exercise this September in Bethesda which will involve a number of Government agencies and academia.

HEALTH CARE COSTS

Senator EAGLETON. Very good.

There is one statistic I think you ought to have on your table. This note says that in 5 years, medicare and medicaid—I know medicaid is given to people other than senior citizens—in 5 years medicaid costs have gone from $12 to $53 million.

Dr. BUTLER. It is important to remember that the reason we have an increase in health care costs with age is because we no longer have the health costs once associated with the younger years, and women have a drastically reduced incidence of morbidity and mortality in childbirth. Thanks to the progress of biomedical research, children and infants don't have the same illnesses that they once did.

So, some of this drain on the health budget presumably represents what we wanted, namely, to defer health costs to the later years.

But I do think we have to address those more costly diseases.

Dr. Tower spoke about the PETT, positron emission tomograph, which is particularly interesting to us. This is a new and important device which will be on the NIH campus relatively soon. It will provide unique opportunities to better understand senile dementia because it uses a very precise technique for direct measurement of cerebral blood flow, oxygen consumption, and the way in which the brain utilizes a variety of different metabolic pathways. So we are hopeful that, in coordination with the neurology and mental health institutes, we can advance the understanding of this very pervasive disease.

DIFFERENTIAL LIFE EXPECTANCY

Senator EAGLETON. The statement on page 3 of your statistics, it says there are 146 women for each 100 men over 65.

Will that figure go up as more and more women will be working at jobs, et cetera, where some might get hypertension?

Dr. BUTLER. What is fascinating is that in all societies where there are data, as women join the work force, they continue to have a rise in life expectancy. Sweden and Japan are examples.

In collaboration with the Census Bureau, we projected that the year 2030, instead of there being a 7-year difference favoring women over men, there will be a 9.9-year difference.

We were most anxious to include women in our Baltimore longitudinal study—they had not been part of the study for the first 20

years of its existence. This study looks at people over time. With the help of Congress we have now introduced women into the study, in order to gain a better understanding of why there is this difference in life expectancy. Is it the immune system that plays a role? Is it hormones? How much are genetics involved? Nutritional elements? We take very careful dietary histories, for example.

We also have a great interest in the differential life expectancy among racial and ethnic groups in the United States, because there are many racial and ethnic groups that do not enjoy the same life expectancy as other Americans.

Senator EAGLETON. Do black women have the same 7 years as do black men?

Dr. BUTLER. No. It runs more like 5.4, if I remember my facts correctly. I would be very happy to obtain that information, if you would like.

[The information follows:]

The data we have from the National Center for Health Statistics does not separate blacks from other minorities. For minorities as a whole, women have an 8.5-year advantage over men at birth and a 3.8-year advantage at age 65.

MINORITY LIFE EXPECTANCY

Senator EAGLETON. What about Hispanic?

Dr. BUTLER. We are just beginning to develop some data which will involve black Americans, Hispanic Americans, and white Americans.

Some of the data from the State of Colorado show a shocking life expectancy among Hispanic Americans of about 57 years. This contrasts with the aggregate average of about 72 years. It is really a dramatic difference. We are not sure it is fully accounted for by inadequacies of health care. There might be other habits that would be very valuable for us to understand better, and, of course, very valuable for the groups affected.

BUDGET INCREASES

Senator EAGLETON. You are developing quite a constituency as reflected in the whopping increase.

I'm talking about 1978 to 1979. In 1978, $37 million; 1979, $56 million.

That is an increase of 56 percent.

Dr. BUTLER. I would like to comment, if I might, in that regard.

I think I can very happily say that already we have had a quadrupling of research grant applications over the last 3 years, and a steady increase in the quality.

Our pay line, that is, our priority scores, are in line with other NIH Institutes.

American scientists have become interested in aging, and have submitted applications. Because they are outstanding people in the field, it looks like we are in a position to be able to say that this addition which we received over the last year is going to be wisely used and add appreciably to the science base.

Senator EAGLETON. We couldn't throw more money at you than you can absorb?

Dr. BUTLER. No. I wanted to make that point.

I think it is also important to note that the percentage of the National Institute on Aging, within the totality of the National Institutes of Health budget, still runs less than 2 percent.

Senator EAGLETON. I know. It's tiny.

Dr. BUTLER. It is very tiny.

5-PERCENT DECREASE

Senator EAGLETON. Give us your lower 5 percent.

Dr. BUTLER. We share precisely the view that Dr. Fredrickson has expressed, and others here. We must preserve investigator-initiated research. That is certainly counted as one of our absolutely top priorities so as to make certain that we expand the curiosity and interest of American scientists in the field of aging.

We want to do everything we can to protect our research grants, so reductions would come from the other categories to the extent possible.

SOCIAL AND BEHAVIORAL RESEARCH

Senator EAGLETON. Can the Institute justify a goal of extension of behavioral and social research to prepare individuals for longer lives if society is willing to fund concomitant social programs for the elderly?

Dr. BUTLER. If the social behavior aspects are underfunded?

Senator EAGLETON. Yes.

Dr. BUTLER. One of the exciting things about legislation that created the Institute was that it mandated a complex, broad-scale approach to this major social challenge, the expansion of the number of older people.

Since we have been on an absolute slope of growth so far, we have been able not only to maintain, but appropriately to expand, important work in the biology of aging—neurosciences, and so on, while at the same time creating a better balance in the social and behavioral sciences.

These fields are not as disconnected from each other as one might think. Retirement is an example. As you know, there has been a major change in Federal legislation, ending mandatory retirement in the Federal sector, and moving it up to 70 in the private sector.

Senator EAGLETON. Congress knew precious little about a lot of things when it passed that.

I voted for it.

Who wanted to be soft on aging? Everybody raised their hand. But I'm not sure we knew what we were doing.

That is what you are telling us, in a nice way.

Dr. BUTLER. It would be highly irregular for me to do that.

I only wanted to make the point that sometimes there is too artificial a division between the social and behavioral sciences and medicine.

An example is bereavement, the loss of a loved one. Another example is the nature of nutrition and, food preferences.

These examples signify a clear relationship between the psychosocial and medical aspects of aging.

PUBLIC INFORMATION

Senator EAGLETON. Here is one I would like to ask you. Elderly people, of course, worry more about their health than do younger people.

That is understandable.

There are more myths, I think, that sort of float around. In these senior citizen apartment complexes, section VIII, et cetera, the rumor mills go around about health care, what is good for you, what is bad for you, et cetera.

We have some nutrition programs for the elderly, and so on, and so forth.

There are two problems. One is getting information from NIH to the practicing physicians.

That is a big problem, which you are constantly coping with, and we will probably hear a little bit about that from the Library of Medicine, I guess.

How do we get accurate information out to the lay people, in a form that is intelligible, not overly done with scientific terminology, that can put to rest some of these myths that go around?

Dr. BUTLER. We take that very seriously.

We have been surprised to find out that the NIA, among all the offices of the National Institutes of Health, has just an enormous amount of mail. There are questions about lifespan extension, about health, about needs for information, to cite just a few examples.

And to the degree to which we are able, in terms of funds, we are trying to create useful fact books on aging.

"OVER EASY"

Senator EAGLETON. Have you ever been approached at your institute by a TV program called "Over Easy"?

Dr. BUTLER. Yes. As a matter of fact, not infrequently, I have participated in this program for the purpose of providing information.

Also, we created a booklet over a year ago, on a subject which had been well known in the United Kingdom, but not here; namely, accidental hypothermia. As people get older, their regulatory apparatus is not as effective. They don't shiver as well, and their capillaries don't contract as effectively as younger people's. They may not perceive a drop in temperature in their environment as well. And it is not at all rare for an older person to slip into a kind of coma as a result of this occurrence, particularly in the colder areas of the United States.

So we created a booklet on this subject, for which our Information Office won an award.

In the middle of the winter "Over Easy" was kind enough to indicate the free availability of this booklet.

Most nursing homes don't have low-termperature reading body thermometers, nor do most emergency rooms.

In the United Kingdom, they have had a great deal of attention to the issue of the old and cold.

Accidental hypothermia can be misdiagnosed as a diabetic coma, or a stroke, or any number of conditions.

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This is one example of what we have been trying to accomplish in the area of information dissemination to the public.

NEWSLETTER

Senator EAGLETON. For instance, these big national organizations, that send out monthly, maybe more often, news letters; then the labor unions, United Auto Workers has a very active program, and they send out news letters, and what have you.

Then there are news letters in these senior citizens' high-rise buildings, they have a bulletin.

There is a network of communication out there.

Maybe you folks could use, or latch on to that with some meaningfully written advice or articles or what have you. The booklets you refer to are a little bit more elaborate than what I was contemplating.

Dr. BUTLER. We do that. We have strong ties with "Senior Citizens' News," of the National Council for Senior Citizens.

We have these organizations on our mailing key for all information that would be important for them to know.

One example is asbestos, which was mentioned by Dr. Rall in his presentation this morning.

As you can imagine, the shipyard workers of World War II are now in an age group that are of some concern to us.

We went to some special effort to reach this constituency of older people with our concerns so that they would be aware of the potential dangers of exposure to asbestos.

We have tried to capitalize upon the existing network of aging groups which is just incredibly extensive.

Senator EAGLETON. I think that network could be used. I think many of these senior citizens groups would be delighted to include in one or more of their bulletins, helpful hints, or comments or tips.

Unlike news letters that I send out to my constituents that nobody reads, believe me, in a senior citizen situation, any piece of mail that comes in there is thoroughly read, 9 times out of 10.

Of the questionnaires I send out, our highest rate of return consistently is from senior citizens.

They read it. They are interested in it. So I think there is a network out there that you could use to a great advantage.

Dr. BUTLER. In fact, older people have been extremely interested in the Institute, and particularly in geriatric medicine.

Many of them feel that they haven't received the full attention of their doctor, or that their doctor hasn't been fully sensitive to their particular needs as older people.

So it is a two-way street. We hear a great deal from the older people.

Senator EAGLETON. Thank you very much, Dr. Butler.

QUESTIONS SUBMITTED FOR RESPONSES

[The following questions were not asked at the hearing, but were submitted to the Department for response subsequent to the hearing:]

SENILITY

Question: We have often seen the point made that senility might be mimicked by a wide variety of conditions and that they can be intensified by a lack of understanding on how senility should be treated. In other words, a person who is placed in a nursing home, memory lapse is made even greater because that is simply what is expected of the person in that dependent environment. What is the Aging Institute doing to publicize research in that dependent environment, and what do you think additionally should be done?

Answer: It is true that absence of opportunities to participate in every-day tasks and decisions, common in institutional settings, is likely to produce apathy, dependency, and a diminished ability to function generally. Individuals with organic brain disorders, at least 15% of which are reversible, may also suffer mental decline because an improper diagnosis of "senility" leads to lack of corrective treatment. It has been estimated that as many as fifty percent of the nation's nearly one million elderly in long-term care institutions become institutionalized because they have been diagnosed as "senile." Assumptions about inevitable decline with age, largely due to inadequate education and training in geriatric medicine, sometimes cause health professionals to mistakenly label older persons as senile. Physicians and families may attribute mental decline and behavior changes associated with a variety of temporary conditions to "senility." The resulting failure to initiate appropriate and timely treatment may cause the condition to become irreversible and pernanent. Increased exposure of the health community, and the general public, to the distinct body of knowledge known as "geriatric medicine" will greatly decrease the risk of mistaken diagnoses of "senility" and, often, unnecessary institutionalization and dependence.

The National Institute on Aging is currently involved in consensus development activities in the area of senile dementia and has recently co-sponsored two major conferences on senile dementia of the Alzheimer's type with the National Institute of Mental Health and the National Institute of Neurological and Communicative Disorders and Stroke. One of these conferences resulted in the publication of the book,

Alzheimer's Disease/Senile Dementia and Related Disorders.

There are a number of research leads that need to be pursued in subsequent studies, such as changes in the blood-brain barrier, which restrict the exchange of water-soluble drugs and proteins between the blood and the brain, and the role that aluminum may play in organic brain disease. The Institute is expanding its activities in this area as rapidly as resources permit.

Question: What has been done to coordinate with the Neurology and Mental Health Institutes to set up a comprehensive research program on such organic brain diseases?

Answer: We are planning efforts with the Neurology and Mental Health Institutes to develop a positron emission transaxial tomography (PETT) scanning capacity with the shared use of equipment recently purchased by the Neurology Institute. A companion piece of equipment, a cyclotron, is under consideration for purchase. The PETT scanner allows for noninvasive diagnostic evaluation of brain function, and is potentially an invaluable tool in the study of brain disorders.

TRAINING

Question: Last year, you quoted studies to us that estimated that less than one percent of scientists competing for aging grants have experience in the aging field. At the same time, you mentioned that the number of trainees had been reduced in Fiscal 1979. What is the current status of your participation in the National Research Service Awards Program and other programs to attract young and experienced scientists to the growing field?

Answer: We anticipate supporting 169 trainees in FY 1979. In FY 1980, we expect to support 143 trainees under the National Research Service Awards Program. This decline results partly from a policy to reduce pre-doctoral training, and partly from a reduction of funds. We participate in several other programs which, while not training programs, are designed to attract new investigators to the field of aging. These include the special research awards, clinical investigator awards, and research geriatric medicine awards.

I would like to clarify one point on this subject. While no more than one percent of the scientists competing for aging grants have done doctoral or post-doctoral research on aging, many do have research experience in this field. You are correct in stating that the number of investigators with formal training in aging research is very low.

BASIC RESEARCH MISSION

Question: The Aging Institute was created, if I understand correctly, in part to generate information on which to base social and policy decisions relating to the elderly. In your opinion, does the rationale for increased emphasis on basic research apply to this Institute whose mandated mission is, in part, applied research?

Answer: Yes, part of this Institute's function is to generate information which will be useful in social and policy decision-making. Meeting this goal requires both basic and applied research. Basic research, for example, is helping in the development of normative data on aging. Determining what is "normal" functioning for elderly individuals, rather than applying norms relevant to young and middle-aged adults, will improve diagnostic capabilities and subsequent medical treatment. Our epidemiology program is supporting research that should prove very useful to decision-makers. For example, follow-up studies of the Health and Nutrition Examination Survey supported by our epidemiology program will indicate disease outcomes and provide data for proper nutritional recommendations to prevent these outcomes.

PRIORITIES

Question: Dr. Butler, we have a set of questions that we have been asking of each Institute Director. We would like to have you respond to these, as well. First, what programs within your Institute do you consider the highest priorities and what amount is requested for these activities in your 1980 budget.

Answer: The Institute's highest priorities at this time are nutrition, the new geriatric medicine academic awards, diabetes, and animal models and resources. In FY 1980 we anticipate spending $3.3 million on nutrition, $1.6 million on geriatric medicine academic awards, $2.0 million on diabetes, and $1.7 million on animal models.

RESEARCH PRIORITIES

Question: Last year, you mentioned that because of the President's initiative to support more basic research, funds for some of your behavioral research programs would likely be transferred to basic research areas. Approximately what proportion of this year's allocation will be spent on behavioral and applied research?

Answer: We expect the proportion of the budget spent on behavioral and applied research to remain approximately the same as in FY 1979. We anticipate spending 20% to 25% of our FY 1979 research budget on behavioral and social research, 48% to 51% on basic research and between 35% to 40% on applied research, as distinguished from applications research. These categories are not mutually exclusive. The behavioral and social research category contains both basic and applied research. It is also included in the other two categories. It is very difficult to sort this out in a precise way.

Question: Why do you feel, in the area of aging, that these programs are so important rather than basic research?

Answer: Actually, behavioral research includes basic as well as applied research. I would consider behavioral, applied, and basic research as complementary to one another. At least in the behavioral area, basic and applied research are almost a continuum, with the distinction between them somewhat arbitrary. For example, basic research in neurosciences may lead to differential diagnosis of much behavior currently labeled "senility" and help in development of corrective treatments. Basic research is also being conducted in the social sciences. Research on bereavement will study biological changes that often put an elderly person at risk during the first year after the loss of a loved one.

Question: Could you give us examples of how this type of research has been used in the past, either by the Government in making policy or by the private sector to benefit the lives of the elderly?

Answer: To date, NIA research has not played a direct role in formulating public policy. In terms of benefits to the elderly, a number of projects are proving of potential usefulness. Studies of caloric intake, nutrition, and metabolism in the elderly have led to new ideas in obesity control. Research indicates that inadequate anounts of Vitamin K cause calcium loss in bone, increasing the possibility of hip fracture in the elderly. Other studies have shown that the body excretes unusual quantities of nitrogen when subjected to trauma. This loss appears to inhibit wound healing. In theory, then, planning patient nutrition before surgery to accommodate nitrogen loss would help recovery afterwards. This is especially important for elderly individuals, who often recover slowly. Of major importance are studies at the Baltimore Longitudinal Study which are leading to new definitions of what is normal for the elderly.

QUALITY OF LIFE

Question: More and more, Dr. Butler, we are hearing scientists talk about quality of life rather than simply extending the life span. Would you comment on this is terms of your role at the Aging Institute?

Answer: The primary goal of the National Institute on Aging is to extend the healthy productive years of an individual's life. Basic research in such areas as genetics and cellular aging is primarily concerned with developing an understanding of the mechanisms of aging. The possibility of lifespan extension, however, may result from this research which is aimed at easing the mental, physical, and social problems frequently linked with growing old.

National Eye Institute

STATEMENT OF CARL KUPFER, DIRECTOR

ACCOMPANIED BY:

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PREPARED STATEMENT

Senator EAGLETON. Dr. Kupfer, the Eye Institute.

Dr. KUPFER. Yes, sir. I have a prepared statement, which I would like to submit for the record, with your permission.

Senator EAGLETON. Yes, Doctor.

[The statement follows:]

STATEMENT OF CARL KUPFER

Mr. Chairman and Members of the Committee:

Last year, an important event occurred in the history of the National Eye Institute. This was the publication of Vision Research--A National Plan: 1978-1982, a comprehensive document prepared by the National Advisory Eye Council with the assistance of more than 150 of our nation's leading experts in the visual sciences. Copies of this five-year plan have been widely distributed among members of the scientific community, and the response to it has been most favorable. The plan is helping to focus the Institute's program on high priority areas of basic and applied research. These are areas where there are important scientific opportunities and where the potential rewards, in terms of preventing and curing blindness, are great.

Today, I would like to discuss a topic that was given considerable attention in the Council's report: basic research on the retina. This field has progressed to the point where I believe we are now on the verge of making significant advances against major eye diseases such as retinitis pigmentosa, diabetic retinopathy, and macular degeneration.

Basic Research on the Retina

Diseases of the retina, the eye's light-sensitive, innermost layer, account for nearly one half of all cases of severe visual impairment and blindness in the United States. With few exceptions, retinal diseases are the most difficult to treat, and unfortunately, there is no known way to prevent most of them.

Progress against retinal diseases has been impeded by our lack of basic information about this highly specialized tissue, which contains, among other elements, approximately 125 million interconnected light-sensitive nerve cells called the rods and cones.

Because of the lack of availability of living human retinal tissue for laboratory study, scientists interested in studying retinal disease have turned increasingly to animal models. Although several strains of animals with inherited retinal disease have been investigated since the 1940's, most of the early studies were descriptive; they did not attempt to explain what caused the disease. In the past decade, however, as a result of the development and application of new techniques for studying the anatomy and chemistry of the retina, much has been learned about the mechanisms underlying these disorders.

Enzyme Defects in Inherited Retinal Diseases

A biochemical defect, for example, has been identified in the retinal cells of a strain of mice with inherited retinal disease. This defect is a deficiency in an enzyme (phosphodiesterase) that is essential to normal cellular metabolism. It has been shown that this abnormality occurs before the visual cells in these mice begin to degenerate, which suggests that the defect is the cause rather than the result of the disease.

Last year, another important discovery was made. The same enzyme defect that had been found in the mice was identified in the retinal cells of a strain of Irish setter dogs with inherited retinal degeneration. This suggests that this

enzyme abnormality may be associated with retinal degeneration in other species, including man. Although human eyes differ from the eyes of nonprimates in many respects, the rod photoreceptor cells of all vertebrates are remarkably similar.

Other Possible Causes of Retinal Disease

Another interesting finding is that at least one type of human retinal degeneration may result from the absence of a protein in the retina that normally takes up vitamin A and assures its use by the retinal cells. This protein was found to be missing in a donor eye from a man who had suffered from a form of retinitis pigmentosa. The implication of this discovery is that in such an eye, although vitamin A may be readily available, because of the lack of the protein, the retina is incapable of metabolizing it properly.

Therefore, it may be that there are at least two kinds of biochemical defects that underlie diseases like retinitis pigmentosa: the first, a defective enzyme; the second, an absence of a protein receptor for vitamin A. There may well be other such defects that could account for the varying clinical features and prognoses which characterize this group of disorders.

Further evidence to support this view is the discovery of an enzyme defect in the blood of people with a rare retinal disorder called gyrate atrophy which is similar in many ways to retinitis pigmentosa. This is the first demonstration of a specific inborn error of metabolism associated with a human retinal degeneration. Scientists are now trying to find ways of correcting this chemical defect with special diets. If they are successful and if metabolic errors are found to be associated with other retinal disorders, it may be possible to develop treatments for these disorders as well. It may also be possible to diagnose these diseases prenatally and to mount screening programs for carriers.

Basic Research on Diabetes and the Eye

Progress is also being made against another kind of retinal disease, diabetic retinopathy, which is the leading cause of new blindness among adults in the United States. It is now possible in many cases to forestall blindness from diabetic retinopathy and even restore sight to some of those already blind from this disease. The development and testing of new treatments for diabetic retinopathy is a high priority of the National Eye Institute. But we are also emphasizing basic research in hope of learning how to prevent the ocular complications of diabetes. Several studies are aimed specifically at detecting the earliest diabetic changes in the eye, particularly those that take place in the cells that form the walls of the tiny retinal blood vessels. In diabetic retinopathy, these vessels weaken and leak fluid. It is this fluid leakage, particularly when it occurs in the macula, the area of the retina that furnishes sharp, central vision, that causes people with diabetic retinopathy to lose their ability to read.

We now know that the breakdown of the retinal blood vessel walls in diabetes begins before any signs of retinal damage are visible to the ophthalmologist. This evidence has been obtained through a remarkable new electronic technique (vitreous fluorophotometry) which can detect leakage from retinal vessels of minute amounts of an injected fluorescent dye.

This new technique is expected to be a valuable tool in testing the effectiveness of new treatments for diabetic retinopathy that are directed toward preventing leakage from retinal vessels. For example, it has been used to demonstrate that reversal of diabetes in rats can eliminate the leakage of fluid from retinal blood vessels.

Another possible approach to the prevention of diabetic retinopathy has been suggested by the discovery of an enzyme (aldose reductase) which triggers the formation of so-called sugar cataracts in the lenses of diabetic rats. There is

now evidence that this enzyme is present in other ocular tissues and elsewhere in the body. We have concluded that this enzyme may contribute not only to the development of diabetic retinopathy, but also to the development of other complications of diabetes, such as nerve degeneration. For example, tissue culture studies have shown that this enzyme is present in the cells which constitute the retinal blood vessels. There, it may be responsible for the destruction of vessel walls observed in diabetic retinopathy. Several chemical compounds that interfere with this enzyme's destructive action have been developed and tested in the laboratory over the past few years. A search is now underway for even more potent drugs which could prevent or reverse ocular and other diabetic complications in man.

Progress in this field is a good illustration of how fundamental research, which in this instance began 14 years ago with biochemical studies of the rat lens, can lead to important advances against major disease problems.

Need for Basic Research on Macular Degeneration

So far, Mr. Chairman, I have discussed research progress and opportunities in inherited retinal disorders which affect the young and in the prevention of blindness from diabetes which most often strikes those in the prime of life. I would like to conclude with a brief discussion of what is generally agreed to be the most serious eye problem facing older Americans, senile macular degeneration. This aging-related disease robs thousands of otherwise healthy older Americans of their ability to read and carry out normal daily activities. It is a condition which we are powerless to prevent and for which no adequate means of control or cure has yet been found. According to the U.S. Bureau of Census, the number of people in the U.S. older than age 55 will increase by more than 123 percent over the next 50 years, and the number of people over age 85 will increase by approximately 300 percent in the same period. These projections have grave implications for the future prevalence of visual impairment from such aging-related eye disorders as macular degeneration.

We do have some hope that, at least in the early stages of macular degeneration, laser treatment may be helpful. Accordingly, during the past year, the National Eye Institute provided funds to support a multicenter clinical trial of this therapy, which we expect will get underway within the next few months.

Our long-range hope, however, lies with basic research on the macula. It now appears that a few naturally-occurring and experimentally-induced retinal degenerations in animals may be useful as models for human macular disease. In its five-year research plan, the National Advisory Eye Council highlighted the problem of macular disease and identified promising research leads that could be pursued. I think that through the Council's report, scientists have become more aware of this problem and of the several opportunities for productive research. I am therefore optimistic that progress in this field will begin to accelerate.

In conclusion, Mr. Chairman, to support a continuation of these and other vision research activities in the coming year, the National Eye Institute's budget request for FY 1980 is $104,528,000.

PROGRAM PLANNING EFFORTS

Dr. KUPFER. I would like to highlight some of the activities this past year, and really just focus on a few topics.

The first is that we have this past year completed the second vision research program plan.

The first such plan was completed in 1975, and in this second plan the National Advisory Eye Council and we have documented in greater detail the determination of research needs and opportunities in each of the disease areas with which we are concerned. From these, we have come up with a system of priorities that should help determine the general direction of vision research in the United States over the next 5 years.

We have to date distributed some 15,000 copies of this plan in response to requests and I think this planning procedure will prove to be very effective in shaping the direction of vision research in the years to come.

I would now like to highlight some interesting areas of recent research activity, Senator Eagleton, if I may, by calling your attention very briefly to a diagram cross-section of an eye.

NORMAL EYE—A DIAGRAM

You might think of this diagram in terms of a tennis ball cut in half. The front of the eye has the clear cornea, through which light comes to be focused on the very sensitive retina, which receives the light and converts it to nerve impulses which go to the brain by way of the optic nerve, allowing us to see.

Underneath the retina is a blood-rich tissue, the choroid, which nourishes the retina; and then in back of the choroid is the sclera, which in the front we can see as the white of our eye. The sclera continues throughout the back of the eye, and is also white in color.

RETINAL DEGENERATION

So in the case of degeneration of the retina and choroid, if an eye doctor looks into the eye, he might be able to see the bare white sclera in the areas where the choroid and retina have disappeared.

One of the major problems that we are confronted with in the United States, and as a matter of fact throughout the world, are a group of degenerative diseases of the retina and the choroid. Of these, retinitis pigmentosa is one of the most devastating.

If we place a camera at the front of the eye and take a series of photographs of different parts of the back of the eye, we can put these together to form a montage such as we have here. You can see that this area here, which is somewhat yellowish in color, actually is the optic nerve as seen here in this drawing. To the side of the optic nerve is a small area called the macula, and this is a part of the eye that has the highest ability of visual acuity, or sharp, central vision.

You can see the pinkish color of the retina and choroid elsewhere, and this is just a small portion of the back of the eye that an eye doctor would see when he looks in with his ophthalmoscope.

GYRATE ATROPHY

In one type of choroidal-retinal problem, a major breakthrough has taken place in terms of our understanding the basis of this disease entity. For the first time, a specific enzyme defect has been determined to be the basis of a specific retinal degeneration.

Here is a series of photographs taken of the back of the eye of a patient with this condition, called gyrate atrophy. We call it that because of the scalloped edges of the retinal lesions.

Again, one can see the optic nerve, as in the normal eye. The macula is still preserved. But one can see that there has been severe degeneration of the choroid and retina, with scarring, and the white sclera can be seen showing through these lesions.

This is a very devastating condition which usually begins in the first decade of life, and by the age of 30 or 40, many patients with this disorder have become totally blind.

Now, the significance of the condition is that with the results of basic research, laboratory research that determined that a specific enzyme is missing, there now is the definite possibility of two forms of therapy.

One is to provide high levels of vitamin B_6, which we know in some cases will improve the condition from a biochemical point of view; and the second possibility is to put such patients on a very special diet.

So here is a very good example of what has been learned in the laboratory being translated into a practical, therapeutic regime.

And, I think in the next 3 to 5 years we will be able to determine whether in fact these forms of therapy will slow down or actually inhibit the progression of this retinal disease.

Senator EAGLETON. That begins as often as in the first 10 years?

Dr. KUPFER. Yes, sir.

Senator EAGLETON. What is the first indication?

Dr. KUPFER. Night blindness.

The retina consists of two general areas: the very small area of the macula is the only part of the entire retina with which we can see very fine print, and it also is the part of the retina that we usually use under such lighting conditions as we have here in this room.

As soon as the levels of light fall, if we were to go out on a moonlit night for instance, we use the entire periphery of our retina to see to get about; and that is the first area to be damaged in this particular condition.

So the first sign is the child is unable to get about, particularly in the evening.

Senator EAGLETON. What is the point of no return, of it going undetected?

Dr. KUPFER. As long as there is some residual, normal retinal function, there is the possibility that we can prevent total loss of vision. Naturally, the more functional retina that exists, the better the chance of preserving vision.

And we are at present interested in seeking out young people with gyrate atrophy, not only in the United States, but in Western Europe, to consider whether it would be appropriate to try one of these treatments.

DIABETIC RETIONOPATHY

Two other areas I would like to call to your attention have to do with the interrelationship of laboratory, basic research with clinical applications.

In the case of diabetic retinopathy, we have made great strides in the therapeutic use of laser light, reducing considerably the rate of blindness of patients with diabetic retinopathy.

We are now trying not just to treat this condition, but to prevent it. We now have, as a result of laboratory research, an electonic technique whereby we can actually measure the earliest detectable diabetic defects in the blood vessels of the retina.

These retinal blood vessels ordinarily are completely impermeable to a harmless dye that is injected into the blood stream for diagnostic purposes. But the earliest sign of diabetic retinopathy, before anything else can be seen, is a leakage of this dye from these blood vessels.

This technique, which has been tested, in a number of laboratories, can now be applied to patients, giving us an important new tool to use in a study aimed at preventing the development of diabetic retinopathy by identifying it at its earliest stage.

Senator EAGLETON. Assume that this technique works and it is detected early on; what is the treatment recommendation?

Dr. KUPFER. We will start a rather large clinical trial in which patients will be put on either one of two medical treatments, or combine the medical treatment with very selective laser photocoagulation in an attempt to slow down or stop the development of a much more severe form of retinopathy.

MACULAR DEGENERATION

And finally, as Dr. Butler indicated, as the population ages, we are increasingly faced with the chronic, disabling conditions associated with aging. In ophthalmology, a major aging-related cause of visual disability and blindness in the United States, macular degeneration, is becoming more and more prevalent.

Macular degeneration, as the name implies, is a loss of the retina in this particular area. The patient's peripheral retina is intact and he or she can walk about, but is deprived of the ability to read, to see clearly, to see the face of grandchildren or neighbors, and to do such things as watch television and the other activities that we depend on so much in terms of our day-to-day living—being able to cook, and to take care of one's self.

This is a very major problem and here we are really just beginning to begin very intensive basic research in the laboratory to determine what are the significant differences between this part of the retina, which seems so subsceptible in the aging process, and the remainder of the retina, which seems generally to survive aging quite well.

So, the continuum between what is done in the laboratory and what eventually results in a proven diagnosis and treatment must continually go on.

I think I have discussed important examples in which progress is at different stages.

PROGRAM REDUCTION

Senator EAGLETON. Taking those three very, very interesting examples, Dr. Kupfer, and then taking into account the recommendations and directions, as set forth in this vision research national plan, is a half-million dollar cut in your institute consistent with progress on the three things you are talking about in the national plan?

Dr. KUPFER. Well, sir, if we are looking at a half-million dollar reduction for a 1-year period of time, I think that we have generated so much momentum in these three areas and others that I think

we will be able to manage to keep up an active research program in these three areas.

Senator EAGLETON. Was another Institute cut?

Dr. FREDRICKSON. There were several others in which there were relatively small decreases.

The largest single cut was in allergy and infectious diseases. These are all primarily developed on the basis of adjusting for the amount of training to a preceding year, Senator.

Senator EAGLETON. I'm sorry. I didn't mean to cut you off.

Dr. KUPFER. No, sir. I was saying I think we could sustain the momentum in terms of a 1-year cut. I think after that it would be perhaps a different matter. But I think for 1-year, we could manage to maintain this momentum.

Senator EAGLETON. You will give us, also, the bottom 5 percent.

Dr. KUPFER. Yes, sir.

Senator EAGLETON. Very good, Doctor.

Dr. Fredrickson, I'm just going to put this item on the record. We will talk about it at a later time. I don't solicit any comment from you instantly.

We do have a letter from Mr. Bohen, the Assistant Secretary for Management and Budget, asking for a reprograming of $3 million to start the new National Center for Health Care Technology, and take that $3 million out of the NIH budget.

There is a list of where the cuts would be made, per institute. The Eye Institute would be cut $70,000; Cancer Institute, $1.3; and various dollar amounts inbetween.

I don't ask for any comment from you now. Take note of it.

Thank you, Dr. Kupfer.

QUESTIONS SUBMITTED FOR RESPONSES

[The following questions were not asked at the hearing, but were submitted to the Department for response subsequent to the hearing:]

DIABETIC RETINOPATHY

Question: We understand that you are making a great deal of progress in the area of diabetic retinopathy through your clinical trials program, Dr. Kupfer.

Please tell us about this in terms of what kind of progress you are making and what is being done to get this information out to the practicing physician?

Answer: Vascular and circulatory abnormalities of the eye are the leading causes of new blindness and visual impairment in the United States today. The most prevalent of such disorders are due to diabetes. The clinical manifestations of diabetes include ocular complications such as retinopathy, cataracts, neovascular glaucoma, and disorders of the vitreous. Because of the magnitude of the public health problem, and the vision research community's recognition of the need, about 15% of the NEI FY 1978 budget went to the support of research which relates to the etiology, diagnosis and prevention of these disorders. Most of this support went for nearly 100 investigator-initiated research grants for fundamental and clinical studies.

During fiscal year 1978, National Eye Institute support of research on the causes, treatment, and prevention of diabetic retinopathy and other ocular complications of diabetes was over $12 million. These funds supported a wide array of studies ranging from biochemical and physiological investigations designed to elucidate the detailed pathogenetic events associated with diabetic eye diseases in general, to clinical trials of new treatments for diabetic retinopathy in particular. Especially noteworthy are (1) the continuing success of the Diabetic Retinopathy Study in establishing a scientific basis for the use of photocoagulation in the treatment of proliferative diabetic retinopathy; (2) the new multi-center clinical trial -- Early Treatment Diabetic Retinopathy Study -- to determine the best timing during the course of the disease to administer photocoagulation or other therapies; (3) the continued development of plans for eventual clinical evaluation of chemical substances that inhibit the enzyme aldose reductase and thus have potential value in treating complications of diabetes in the lens, peripheral nerves, and retinal vasculature; (4) the initiation of clinical trials of therapies for other retinal-vascular disorders -- the Macular Disease Photocoagulation Study, the Branch Vein Occlusion Study, and the Prematurity, Vitamin E, and Retrolental Fibroplasia Study; (5) fundamental and clinical research studies utilizing new techniques to examine the normal and pathological properties of the blood-retina barrier and to improve capability for early diagnosis of retinopathy; and (6) increased activities on knowledge transfer with respect to the treatment of patients with diabetic retinopathy.

The National Eye Institute is supporting three multi-center clinical trials to evaluate the efficacy and safety of treatments for diabetic retinopathy. These are as follows:

(1) Diabetic Retinopathy Study (DRS). The DRS is a multi-center clinical trial to evaluate the efficacy of photocoagulation therapy in the treatment of diabetic retinopathy. This random-

ized, controlled study, involving over 1,700 patients at 15 medical centers, is in the data-analysis and the patient follow-up stages. Results of the study have clearly demonstrated that photocoagulation is effective in reducing the risk of severe visual loss and in inhibiting the progression of retinopathy. Some side effects of treatment, small losses of visual acuity and constriction of the peripheral visual field, were also found.

(2) Diabetic Retinopathy Vitrectomy Study (DRVS). The DRVS is a multi-center clinical trial to evaluate the efficacy of vitrectomy when performed in the first six months after vitreous hemorrhage secondary to diabetic retinopathy, as compared to the more usual practice of waiting twelve months after vitreous hemorrhage to remove the vitreous. In addition, natural history data is collected in systematic fashion on patients who have diabetic retinopathy with extensive formation of abnormal blood vessels and/or early retinal detachment, but without extensive vitreous hemorrhage. The findings of this study will be published and disseminated to the medical community.

(3) Early Treatment of Diabetic Retinopathy Study (ETDRS). The objectives of the ETDRS are to determine whether treatment of the early stages of diabetic retinopathy, by aspirin or dipridamole, or by prompt photocoagulation, or by a combination of drug and laser therapy, is effective in decreasing the rate of development of severe visual loss, when compared to no treatment or to deferred photocoagulation; to determine the optimal time to initiate photocoagulation treatment in diabetic retinopathy; to monitor closely the effects of diabetes mellitus and of photocoagulation therapy on visual function; and to develop natural history data that can be used in developing etiologic hypotheses and in identifying risk factors for diabetic retinopathy.

The first general meeting of ETDRS investigators was held in November 1977 to initiate the planning phase of the study. Subsequent meetings have been held throughout 1978 to clarify the details of the study's design and to prepare the Manual of Operations. These activities are near completion and recruitment of patients is expected to begin by June 1979.

The NEI has conducted several activities to disseminate the findings from the diabetic retinopathy clinical trials. Some examples follow: displays have been presented at the annual Academy of Ophthalmology meetings describing the DRS and DRVS studies; a course for clinicians was given detailing DRS study findings, implications, and applications of these findings to patient management; NEI staff, study participants, and Academy officials have been working toward the preparation of a manual for the practitioner which will include case studies of diabetic retinopathy and their suggested management; over 2,500 copies of each of the two DRS journal publications have been distributed; manuals and study booklets of the DRS and DRVS have been used by numerous clinical investigators for planning other clinical studies in the visual sciences and for teaching purposes; and the NEI has responded to thousands of lay inquiries relative to diabetic retinopathy. NEI fact sheets have been prepared and distributed describing the DRS, DRVS, ETDRS and Diabetic Retinopathy;

and letters have been sent to all ophthalmologists in the U.S. announcing the close of recruitment for the DRS and the availability of published study findings.

CATARACTS

Question: Please describe the activities and the purpose of the Cooperative Cataract Research Group.

Answer: The purpose of the Cooperative Cataract Research Group (CCRG) is to apply the combined efforts of a group of scientists performing research on the lens in such a manner as to accelerate progress in learning the cause and nature of cataracts in humans and to develop methods for preventing their occurrence. The group is structured on an "area of research" basis, with the leader of each of the areas of research being a member of the overall guiding body, the Executive Committee. Within each area of research, meetings are arranged for early dissemination of information, for development of collaborative studies and for general trouble-shooting. The acquisition of adequate supplies of human lenses for research studies is a continuing problem. A first objective, the development of a human cataract classification scheme, has been achieved.

As a result of the CCRG stimulus, the number of studies on the human lens has increased appreciably. Its success has encouraged lens researchers in Europe and Japan to form similiar cooperative programs.

Question: Where do we stand in the prevention of cataracts, especially among the elderly?

Answer: At present, there are no known drugs which prevent or delay the development of cataract in the elderly. However, animal studies with selected types of cataract offer some degree of optimism that this important objective will ultimately be achieved. Thus, in diabetic animals, it has been possible to slow the rate of cataract development through the use of a specific class of drugs, inhibitors of the enzyme aldose reductase. Studies are in progress seeking ways to test and apply these drugs to diabetic humans.

Question: Do you have anything new to report in the area of lens implants?

Answer: Recognizing the importance of intraocular lens implants, we have initiated a long term study of the value and safety of lenses which are inserted into the anterior chamber of the eye. Information concerning the efficacy and safety of intraocular lenses should be forthcoming during the next 3-4 years.

INTER-INSTITUTE COOPERATION

Question: Glaucoma and cataracts are areas which affect many elderly people.

Could you give us some examples of how you deal with the Aging Institute in these two areas in terms of inter-institute cooperation?

Answer: Cooperation between the National Eye Institute and

the National Institute of Aging is a continuing activity, particularly in the areas of glaucoma, cataract, and retinal degeneration. The NEI has asked the NIA to comment on our program announcements soliciting research grant applications in these areas. This is done to ensure that we are not addressing major research areas of primary interest to another institute, as well as to provide information on overlapping program interests. Although these research areas fall primarily within the programmatic interests of the NEI, the NIA has the option to obtain a secondary assignment on those grant applications relevant to its mission.

Certainly, the application of basic knowledge in aging to the clinical setting is another area where cooperation is needed. In this respect, the Director, NEI, has met with the National Advisory Aging Council; and the Director, NIA, is scheduled to discuss areas of mutual interest with the National Advisory Eye Council.

INFORMATION DISSEMINATION

Question: Walk us through, Dr. Kupfer, how you would disseminate the results of any positive clinical trials you might have to physicians and lay people throughout the United States?

Answer: A well thought-out plan for dissemination of clinical trial results must include consideration not only of appropriate media and target audiences but also the right of participating patients and their physicians to be thoroughly briefed on these findings before there is any public announcement. This principle was adhered to in a carefully orchestrated effort to release information on the National Eye Institute's recently completed Diabetic Retinopathy Study of photocoagulation treatment.

In the early months of 1976 when the beneficial effects of photocoagulation treatment had become apparent, a decision was made to prepare a preliminary report of these findings for publication in a leading ophthalmology journal and to announce the findings to the press. This was to be the first public announcement of results from this clinical trial. Prior to this public release, however, plans were made to inform participating physicians of the findings. Target dates were also set for notifying all study patients and their own private physicians of these results.

Through a special arrangement with the journal, preprints of the scientific report were mailed in advance of publication with a letter of explanation from the NEI Director and Study Chairman to all 10,000 ophthalmologists in the United States. This was done to insure that ophthalmologists treating patients with diabetic retinopathy would not be taken by surprise by announcements in the news media.

Because widespread public and news media interest was expected, a press conference was planned for the same day that the journal was to be published. Spokesmen from the National Eye Institute, as well as ophthalmologists and statisticians directing the study, were present to answer questions at the conference which was well-attended by the science writing press corps. Press kits providing background material and illustrations relating to the study findings were also distributed. A press release was also issued the same day to members

of the science press not in attendance at the conference.

Excellent coverage ensued over the next several days, weeks, and months in leading national publications, on the networks, and in local newspapers and broadcast media throughout the United States. Although there had been some amount of ambivalence among study participants about releasing the findings to the general public for fear of misinterpretations, the desirability of preparing and distributing carefully-worded materials to the press soon became apparent.

An exhibit summarizing the study results was prepared for display at the fall meeting of the American Academy of Ophthalmology. Booklets originally prepared to accompany the exhibit have since been reprinted in large quantities and distributed at local medical meetings throughout the country where physicians participating in the study have made presentations. In addition, numerous follow-up articles were prepared for publication in various general and professional media, most of them with the help of the National Eye Institute's Information Office. These ranged from professional publications such as Diabetes Outlook to the American Legion Magazine and home magazines such as Better Homes and Gardens. Fact sheets and other informational materials were also prepared in response to requests for information on photocoagulation treatment from the general public.

A 13-minute sound film and narrated slide show which illustrated clinical trial principles using the Diabetic Retinopathy Study as a model were produced and presented initially at the American Academy of Ophthalmology meeting. They have subsequently been shown to students and faculty in medical schools and schools of public health throughout the United States and abroad. A Spanish language version of the film has also been produced. The movie won the Golden Eagle award of the Council of International Nontheatrical Events and has been shown in two international medical film festivals.

Most recently, the National Eye Institute assisted in closeout activities for this trial by drafting a letter which will be sent to all ophthalmologists in the United States. This letter again summarized the study findings, updated them, and thanked ophthalmologists who referred patients to the study. A brochure explaining the study results to participating patients has been printed, and an interpretation of the results for primary care physicians has been published in the "From the NIH" column of the Journal of the American Medical Association.

Although a variety of media has been used to disseminate information about the study, our primary target has been the physician in practice. It is vital that he or she understand how the findings can be translated into improved management of patients with diabetic retinopathy and prevention of blindness. Secondarily, we have tried to acquaint diabetic patients themselves, as well as their families and friends, with the fact that an effective treatment for diabetic retinopathy does exist.

Question: Are you satisfied with the degree of awareness that the public has about preventable and treatable vision disorders?

Answer: Through efforts by the National Eye Institute and those

of major professional and voluntary organizations such as the American Association of Ophthalmology, the American Academy of Ophthalmology, the American Optometric Association, and the National Society to Prevent Blindness, the American public has to a large extent been made aware of how certain vision disorders may be presented and treated. Each year the President issues a proclamation declaring the first week in March as Save Your Vision Week and this event is widely promoted in the news media and by professional groups. School and industrial safety campaigns throughout the year aimed at preventing eye injuries, and glaucoma screening programs promoted by prevention of blindness societies and Lions clubs have been especially effective in raising public awareness. Our monitoring of the news media shows frequent articles on eye safety, eye care, and eye disease prevention. Unfortunately, such articles often contain inaccurate or misleading information, or they focus on only a few well-known eye disorders to the exclusion of others.

For this reason, we feel that one of the most cost-effective means of increasing public awareness of prevention and treatment of eye disorders is to work with the mass media and encouraging the development of accurate and interesting articles on this subject. We place a high priority on giving prompt and comprehensive responses to media inquiries. In addition, we try wherever possible to interest reporters in covering this field and provide them with possible leads and useful background information. Added to these efforts, we plan during the coming year to add to our portfolio of brochures and fact sheets on eye diseases and eye research.

Question: What are some examples of programs or media information that you have developed in the past year to help the public become more aware of these disorders?

Answer: In addition to our initiatives relating to the Diabetic Retinopathy Study, another major accomplishment during the past year was to persuade the producers of a new Public Broadcasting Service television program "Over Easy" to devote air time to discussion of eye care. We arranged for the producers of the program, which is aimed at older Americans, to contact a representative of the American Academy of Ophthalmology on the West Coast where the program is taped. On the three occasions so far that this individual has appeared on the show, the National Eye Institute has been mentioned as a source of additional information. As a result, we have received hundreds of letters from viewers of the show, carried on 261 public television stations, asking about prevention and treatment of eye disorders.

In general, as I mentioned earlier, the National Eye Institute placed great emphasis on cooperation with the news media during the past year. As a result of one article on the treatment of cataract which appeared in the New York Times, the NEI received more than 4,000 requests for its booklet on cataract. Articles have also appeared in magazines such as McCall's, Science Digest, Harper's Bazaar, Good Housekeeping, Family Circle and major newspapers such as the New York Daily News, Minneapolis Tribune, Newsday, and the Boston Globe. We cooperated with the producers of the CBS Morning News who prepared a segment last November on macular degeneration research, a large portion of which was taped at the NEI's clinical research facilities. Supplementing these media activities was the distribution of more than 11,000 fact sheets and booklets on eye

disorders and vision research. More than 900 letters were also sent to individuals who wrote us to ask about eye disorders, prevention, and treatment.

In December, I presented a lecture in the NIH Medicine for the Layman series on "The Eye and Diseases." This was well-attended by the public and, I understand, was also well-received. The theme of this lecture, which is to be made available to the public in printed form and on videotape, was prevention and treatment of common eye disorders. Currently, we are cooperating with the NIH's central audiovisual branch in producing television and radio spots on cataracts. In these announcements, patients who have been recommended by their ophthalmologists for cataract surgery will be encouraged to consider having this operation. It is a highly successful procedure about which there is still a considerable amount of public misunderstanding and unnecessary fear.

As important as it is to create public awareness of preventable and treatable eye disorders, it is also important to present factual information on the state of the art in disorders for which there is no effective means of prevention or treatment. And the general public should be made aware of services and devices available to visually impaired people which can help many of them make the most of their residual vision and adjust to their condition rather than pursue false hopes and cures. The National Eye Institute attempts to fulfill these needs in its public information programs.

MYOPIA

Question: Last year, the Committee recommended an emphasis on research into the causes, treatment, and prevention of myopia.

What efforts have you made in this direction and what are your plans for fiscal year 1980?

Answer: The National Eye Institute presently supports myopia research at an approximate cost of one-half million dollars. One Study seeks through carefully controlled clinical and laboratory research to evaluate the visual changes resulting from using specially designed contact lenses to reverse myopia by modifying the curvature of the cornea. This procedure, often referred to as orthokeratology, has sparked considerable controversy. It represents a departure from the traditional viewpoint that the goal of successful contact lens fitting is to avoid any corneal change.

The fact exists, however, that this procedure is being practiced by a growing number of practitioners and has excited the interest of the public through coverage in the general news media. Still, the only source of information about the success of this technique comes from the paractitioners themselves and the data are generally limited and sometimes biased. Nevertheless, there are sufficient positive results documented that the technique can no longer be ignored as a potential clinical procedure. Therefore, the National Eye Institute will conduct studies of the methods used and the results produced. During FY 1980, the Institute will also continue to support other investigations into the medical and surgical treatment of myopia.

BLINDNESS

Question: How many people in the United States are affected by total blindness?

Answer: There are an estimated 500,000 people in the United States affected by total blindness. Of course, this figure represents only a small portion of the more than 10 million people who suffer from visual impairment which are not amenable to further improvement with corrective lenses. Of these, 2 million are so severely handicapped that they are unable to perform routine daily activities and thus may be considered either functionally or legally blind.

Question: Is blindness in the United States growing in real numbers or simply in terms of the size of the population?

Answer: Blindness in the United States is growing in real numbers as the population of the U.S. increases. Also, the increased incidence of blindness is related to the increased longevity of the American population. Studies have shown that over the next 50 years, the number of people in the U.S. older than age 55 will increase by more than 123 percent, the number over age 85, by approximately 300 percent. This has grave implications for the future prevalence of aging-related eye disorders. By applying to these population projection estimates of the current age-adjusted prevalence of the four leading causes of blindness in the United States--cataract, senile macular degeneration, glaucoma, and diabetic retinopathy--the prevalence of these diseases can be expected to increase an average of 160 percent by the year 2030 if nothing is done. On the other hand, positive results from the diabetic retinopathy study have reduced the incidence of blindness from this disorder by approximately 50%. This factor will serve to actually offset the increasing incidence of blindness.

CLINICAL TRIALS

Question: Dr. Kupfer, how about your clinical trials program? How many are you currently supporting and what plans do you have in the future?

Answer: The National Eye Institute is currently supporting through research contracts three large-scale clinical trials. One of these is the Diabetic Retinopathy Study which provided evidence that photocoagulation treatment could reduce the risk of severe visual loss in people with moderate to severe diabetic retinopathy. This trial should terminate during FY 1979. Two other trials, the Diabetic Retinopathy Vitrectomy Study, whose purpose is to evaluate early versus late vitrectomy in the treatment and management of diabetic retinopathy, and a new trial, the Early Treatment Diabetic Retinopathy Study which is attempting to evaluate whether photocoagulation treatment earlier in the course of diabetic retinopathy can slow the disease's progression and thereby be more helpful in preserving vision, are also supported by the Institute. As well, nine grant-supported clinical trials are supported by the National Eye Institute. As part of the Institute's recent comprehensive planning effort, 30 diagnostic and treatment hypotheses were identified by leading vision research experts which merit testing and evaluation through clinical trials. Should the vision community

submit high quality grant applications to exploit these opportunities, the Institute would to the extent of available resources provide support for the most meritorious.

Question: Could you give us an idea of what you are looking for through these clinical trials at the present time?

Answer: Clinical trials supported by the National Eye Institute serve as prospective tests of the efficacy and safety of any medical intervention, whether therapeutic, prophylactic or diagnostic. Their conduct requires reliance on facts rather than on opinions or impressions, the study of disease in defined groups rather than in individuals, the use of systematic rather than improvised procedures, the elimination of bias, and the use of sound statistical analysis.

High quality clinical trials embody the same principles and approaches as other areas of basic and applied science. Clinical investigators first identify a problem of interest and formulate hypotheses relative to the potential resolution of the problem. Then they design and conduct investigations to provide definitive tests for the stated hypothesis. Finally, they evaluate their findings in relation to the original hypothesis and its alternatives. The clinical trial differs from laboratory research, however, in that it deals with patients, utilizes extensive resources (manpower, equipment and supplies), takes several years to complete, and often requires the collaboration of several medical facilities throughout the country, working together within a complex administrative framework.

NEW DEVELOPMENTS

Question: In the past couple of years, Dr. Kupfer, the Eye Institute has received an increased recognition for a strong program and one that is very actively involved in the problems of eye disease and blindness in this country.

In your opinion, what are the major contributions which the Institute has made to the well-being of our society and to biomedical research in general?

Answer: Although much good has been done in the past to provide assistance to those who are already blind, only recently has interest grown in finding new and better ways to prevent and cure blindness, particularly that caused by chronic disorders. And, just recently has the plight of the millions who have partial vision, but do not qualify for benefits due the blind, begun to be fully appreciated.

It is this growing awareness, both of the promise of research and of the full extent of the problem, that in the past quarter century - and especially during the last decade following the creation of the National Eye Institute - has helped propel the field of vision research to the forefront of biomedical science. Today, investigations into the normal and abnormal structure and function of the visual system are not only advancing knowledge of vision and visual disorders but are providing new understanding of basic life processes and systemic diseases. By studying the eye, for example, we are learning how to modulate the effects of diabetes on vision while adding to general knowledge about this devastating and highly preva-

lent disease. By studying the effects of early sensory deprivation on the developing visual system, we are gaining important knowledge of the requirements for the normal development of the central nervous system. By testing drugs against ocular viral infections, we are creating the forerunners of a new class of compounds that may effect cures for a number of diseases for which there is presently no hope. By studying the effects of aging on the protein structure of the human lens, we are gaining important insights into the very nature of the aging process.

As the principal source of support for vision research in the United States and perhaps the world, the National Eye Institute is responsible for providing leadership in this field, for helping maintain the high quality standards that have been established, and for assuring that the primary objective of such studies continues to be the improvement of health and the alleviation of human suffering.

In recognition of this obligation and of the fact that there will never be enough funds to support all worthwhile research proposals, the National Advisory Eye Council, the principal consultative body to the National Eye Institute, in 1974 embarked upon an unprecedented attempt to evaluate the Nation's vision research effort and to develop a structure for priority setting that would focus public and scientific attention on the most pressing problems and most promising opportunities in this field while assuring the continued free exercise of scientific creativity. The Council's report, Vision Research Program Planning, published in 1975, documented the need for program planning during a period of fluctuating health research budgets and at a time when increasing emphasis was being placed on the importance of accountability to the public for research expenditures.

The response by the scientific community, high levels of government - including the Congress - and the public to the Council's first report has been most favorable and enthusiastic. Encouraged by this reaction, the Council began planning a second report which would explore more thoroughly a number of issues that had been raised before and to discuss several new topics which are currently of great interest and concern.

This report, Vision Research, A National Plan: 1978-1982, addressed the need to establish meaningful priorities, particularly in terms of limited funds. The report went on to outline the amount of funds that could most profitably be spent, the areas of greatest need, and established a ceiling on spending. Five major eye disease categories were pinpointed, and stringent priorities set within each category. This highly systematic approach to funding vision research is the key to winning the battle against major eye diseases, not only restoring the visual function of individuals, but greatly reducing cost.

Examples of research advances and estimates of savings associated with these advances follow:

Cataract

About 400,000 operations are performed each year in the United States for removal of cataracts. Ten years ago, each patient required six to seven days recuperation time in the hospital.

Improvements in surgical procedures has reduced this recuperation time down to as little as one to three days, saving an estimated quarter billion dollars a year in hospitalization costs alone.

Glaucoma

Although extensive supporting data is not available, new advances in drug treatment of glaucoma will save tens of millions of dollars, not only in governmental assistance payments, but in time lost from work. There are an estimated 2 million victims of this blinding eye condition.

Cornea

Herpes simplex keratitis is a corneal condition frequently causing blindness and visual impairment. There are approximately 300,000 victims of herpes, large numbers of whom will benefit from the drug Vidarabine. Measured in economic terms, this will probably save millions of dollars in costly medical treatment, rehabilitation, and disability payments. However, because the drug is so new, exact figures are not currently available.

Diabetic Retinopathy

The Diabetic Retinopathy Study showed that over a four-year period, photocoagulation reduced by at least 50 percent the rate of blindness from this disease. The total cost of maintaining those people in the United States who are now blind from diabetic retinopathy is estimated at approximately $320 million. If their blindness had been prevented with photocoagulation, the cost of treatment would have been about $33 million. Thus, the potential benefits that will undoubtedly accrue from this newly-validated treatment are substantial.

PRIORITIES

Question: What programs are your top priorities for fiscal year 1980, Dr. Kupfer, and what is the total amount of these programs?

Answer: Top priority will be given to the following areas:

- The specific anatomy, biochemistry, and physiology of the retinal photoreceptor cells and of the underlying pigment epithelium. These studies should focus on both normal animal and human tissue as well as tissue from dystrophic animals and from humans with retinal disease.

- Application of techniques from such basic research disciplines as psychophysics and electrophysiology to the diagnosis and understanding of retinal and choroidal disease.

- Macular degeneration, especially its relationship to age changes in Bruch's membrane (which separates the retina and choroid); to the formation of abnormal new blood vessels, and to the metabolism of the pigment epithelium-photoreceptor complex.

- The characteristics of the blood circulation within the retina

and choroid, and the cause of the changes which occur in diabetes mellitus and other retinal vascular diseases.

- The mechanisms which normally keep the retina attached to the posterior wall of the eye, and the structural and functional derangements which may contribute to retinal detachment.

- The neurophysiology of retinal organization and visual adaptation, especially in the primate.

- The roles of viruses, particularly herpes virus, their antigenic products, and the host inflammatory responses to these viruses in corneal disease.

- The development of more effective methods to treat corneal viral diseases and to modify the host response.

- Study of the composition, chemical and physical characteristics, and drainage of tears in health and disease.

- Conduct of further studies of the structure, chemistry, and light transmission properties of the normal lens.

- Development of methods of tissue culture of human lens and lens cells.

- Through a nationwide cooperative research group increased study of human senile cataract.

- Application of new biochemical and biophysical techniques to the study of senile cataract.

- Development of methods for tissue culture of senile cataract.

- Design of electronic equipment for documenting cataract development.

- Study of changes in lens carbohydrate and lipid metabolism with aging and cataract.

- Study of the efficacy and long-term effect of intraocular lens implantation following cataract surgery through animal studies and a large-scale clinical trial.

- Further study of the chemical pathways by which diabetes causes or accelerates cataract formation.

- Further development and testing in humans of new chemical inhibitors of diabetic cataract formation.

- Establishment of the relationship of genetic markers to the development of various types of glaucoma.

- Determination of whether glaucoma affects Blacks or other racial and ethnic groups more frequently, earlier in life, and/or more severely.

- Development of a primate animal model of chronic glaucoma for

life-long investigation and stereophotographic documentation of changes induced in the appearance of the optic nerve head. Making subsequent correlations with laboratory tissue studies and explore how much individual variation there may be in susceptibility to injury by a given pressure.

- Evaluation through prospective, controlled clinical research of the risk to vision from treatment of systemic hypertension in patients with glaucoma.

- Establishing factors or tests that may indicate varying susceptibility of individual optic nerves to chronically elevated intraocular pressure. These factors may have predictive value and could serve as a guide to the amount of treatment needed in individual cases.

- Ascertaining the relative influences of physical factors and of metabolic processes in controlling aqueous humor outflow. This may lead to improved treatment and possibly even to prevention of some forms of glaucoma.

- Study of factors which regulate the development of the mammalian visual system and analyze the mechanisms which lead to the formation of highly organized visual pathways.

- Study of the effects of experimental strabismus on the structure and physiology of the visual nervous system in cats and monkeys.

- Determination of the periods in human development of greatest susceptibility to strabismic amblyopia and evaluate the usefulness of visual training and drugs in reversing this condition.

- Development and breeding of animal strains with congenital strabismus and related abnormalities.

- Application of psychophysical techniques to the improved diagnosis of strabismus amblyopia.

- Determination of the cause and development of congenital nystagmus and other uncontrolled eye movements.

- Development and testing of drugs that act on the central nervous system to control abnormal eye movements.

- Application of visual psychophysical techniques to improving clinical diagnosis of retinal and sensorimotor disorders.

The total amount required to fund these program is $104,528,000.

CENTERS

Question: Dr. Kupfer, year after year, the Committee expresses its concern to the NIH about its growing centers program. I understand that NIH now funds over 500 different centers programs and it obviously takes a great deal of funding for this to be accomplished. In effect, this becomes a mandatory portion of the

Institute's budget and these must be funded first before new research grants are awarded.

How do your centers program differ from many others at NIH in terms what you call the "core" concept?

Answer: Most research center grants are awards which support a number of discrete research projects under one "umbrella". Thus, one research grant is used to fund a series of projects. The program project is another award mechanism used to fund a series of discrete research projects. The NEI currently does not fund any program projects.

The NEI core grant is an administrative mechanism used to provide for essential or central research resources and facilities to a group of investigators engaged in visual sciences research. Resources or services are shared by all investigators. The core grant, while supporting such activities as animal services, research photographic services, machine shop services and others, does not support the research activities directly. Eligibility for a core grant requires that the awardee organization have at least four investigators with NEI support, and no less than six independently supported NEI research project grants.

True core grants are not research center grants and should not be considered so in our view. Certainly, core grants may facilitate the establishment of a vision research center; but they provide only a small part of the total support of the center. They support central and resource activities associated with research already underway funded under individual research grants.

National Library of Medicine

STATEMENT OF MARTIN M. CUMMINGS, DIRECTOR

ACCOMPANIED BY:

DONALD S. FREDRICKSON, DIRECTOR, NATIONAL INSTITUTES OF HEALTH

KENT A. SMITH, DEPUTY DIRECTOR (ACTING), NATIONAL LIBRARY OF MEDICINE

H. RICHARD MILLER, ASSISTANT DIRECTOR FOR BUDGET, DIVISION OF FINANCIAL MANAGEMENT, NATIONAL INSTITUTES OF HEALTH

KENNETH S. LEVINE, DEPUTY ASSISTANT SECRETARY FOR LEGISLATION

WILFORD J. FORBUSH, DEPUTY ASSISTANT SECRETARY, BUDGET

PREPARED STATEMENT

Senator Eagleton. All right. Dr. Cummings, National Library of Medicine.

Dr. Cummings. I would like also, if I may, to submit my statement for the record, and provide you with a brief summary.

[The statement follows:]

Mr. Chairman and members of the committee, this year the National Library of Medicine celebrates the 100th anniversary of its production of the world's most comprehensive bibliography of medical literature, Index Medicus, which was conceived and created by the Library's first director, Dr. John Shaw Billings, in 1879. In 1913 this pioneering venture was cited by Dr. William H. Welch of Johns Hopkins as America's greatest contribution to medicine. Since then, its scope and importance have steadily grown as the problem of harnessing and distributing the world's burgeoning biomedical literature has grown.

In its first year of publication Index Medicus listed some 20,000 medical articles from around the world. In this centennial year Index Medicus will provide references to 250,000 articles. Billings derived his listing from approximately 570 journals. Today we index approximately 2,500 medical journals which have been carefully selected from the nearly 20,000 acquired by the Library. More than 10 million issues of Index Medicus have been sold since its publication began and the demand is still growing. In fact, the demand for all of the Library's products and services continues to increase rapidly; overall, by about 13 percent per year.

But as Billings pointed out, " * * * In medicine as in every other profession, art or trade, the supply of the best is never too great and the demand for something better than that which already exists ceases." He was tremendously concerned about access to the scholarly record by the practicing physician. Surely he would be delighted to know that in addition to the copies of Index Medicus which have been distributed, its contents are now available for direct on-line computer searching in more than 840 domestic and 178 foreign institutions. The National Library of Medicine computer programs were used for more than a million searches in 1978.

In 1883, Billings wrote that, "It may perhaps seem to some of you that this Washington Library of yours is not such an important matter as I make it out to be, and it must be confessed that I am not an impartial judge; nevertheless, it does seem to me that the making and keeping of this Library complete is one of the most valuable means of advancing medical science in this country which at present is within our grasp."

In 1968 Congress, by joint resolution, extended NLM's responsibility for providing improved information services by the creation of the Lister Hill National Center for Biomedical Communications within the Library. In a sense, the world had caught up to Billings. Information is now recognized as a fundamental resource of nations, and modern communications and computer technology offer the opportunity for markedly improving the effectiveness of information transfer and utilization. It was to promote, develop, and apply these technologies for the benefit of the health science community that the Lister Hill National Center was created.

To carry out this mission appropriate resources are needed. In the fall of this year the Center's new facility will be completed—well ahead of schedule and well under the projected construction cost. The completion of this building will facilitate the merger of the Lister Hill Center and the National Medical Audiovisual Center into a new center of excellence for research and development in biomedical communications.

A major function of the Center is to support initiatives to develop new systems to provide health practitioners with more efficient access to the information they need as health care providers. A prototype system for information relevant to viral hepatitis has been completed and is undergoing field testing. Further demonstrations and evaluations are planned for fiscal year 1980. Among other applications now being considered is a data base of clinically relevant poison control information.

The National Medical Audiovisual Center, as part of the Lister Hill National Center for Biomedical Communications, will continue to strengthen the instructional components of the national health effort through research in learning theories and educational technologies, the development of prototype instructional learning media and environments, and the sharing of knowledge about effective education systems with those responsible for teaching the nation's health professionals. In fiscal year 1980 the Center will expand its program to include all educational levels but its primary focus will continue to be on improving the continuing education of health practitioners.

The Library's medical library assistance grants and contracts will continue to improve health information services. Resource project grants will aid health science libraries in fiscal year 1980, while resource improvement grants will aid health care facilities in providing more and better information services. Research and demonstration grants will support explorations in biomedical communications. Also grants will be awarded to promote the integration of computer technology with clinical practice and research. Special scientific project grants will support scholarly investigations of major health issues, and publications grants will support the publication of works of importance to the national health effort. Regional medical library contracts will continue to support a library network providing information access to all health professionals.

The research grant program has recently been evaluated by a group of distinguished consultants who concluded that more qualified investigators in biomedical communications are needed, and that increased research in information technologies for health care delivery is required. The National Library of Medicine will therefore emphasize projects that promote research and training related to the use of computers in medicine.

The Library's specialized information services will continue to improve the transfer of toxicology information used primarily for the prevention of disease and the protection of health. This program is responsible for collecting and organizing toxicology data for computerized storage and retrieval systems making it more readily available to industry, universities, government agencies, and health care providers.

Finally, I should like once again to return to the words of John Shaw Billings who in 1891 said, " * * * I may say that the future prospects of the Library are excellent. It is not dependent on the skill or energy, or good will of any one man; * * * The services rendered by a number of those employed in the Library is not a mere matter of money. They are deeply interested in their work and proud of the results, and they can and will carry it on and instruct others who will come after them to do likewise." We plan to continue to operate in this tradition.

Mr. Chairman, in fiscal year 1980 our budget request is $41,431,000. I shall be pleased to answer any questions and supply additional information desired for the record.

LIBRARY RESEARCH

Dr. CUMMINGS. I should say coming at the end of these hearings that good research often begins and ends in a library. A good library should be able to provide my scientific colleagues with a record of what took place before they engaged in their investigations, and it should also preserve the record of their accomplishments, at least as reflected in the publication.

100TH ANNIVERSARY

We have been doing this for our Nation for 100 years. This is the centennial of the publication of Index Medicus, the world's most comprehensive medical bibliography.

When my predecessor, a young surgeon, Dr. John Shaw Billings, started this monumental publication, he and one colleague had to examine the world's output, which then consisted of 570 journals, and some 20,000 articles.

Today we are acquiring more than 20,000 journal titles each year. From this number, we carefully examine 2,500, and index and catalog the material contained in some 250,000 articles.

I should say that the Index Medicus has been sold over the past century, and we passed the 10-million mark in number of issues sold. I think that is a phenomenal record of publication.

The material is so voluminous that it is now compressed and stored in our computer system.

BIOMEDICAL COMMUNICATION NETWORK

We have a network which provides an outlet in some 840 domestic institutions, and 178 medical institutions overseas.

Through this network, the National Library of Medicine last year provided more than a million searches for not only references, but for information and data as well.

This represents more than half the computer searches done in all fields and disciplines. This, too, we believe, is a remarkable accomplishment.

LISTER HILL CENTER FACILITY

I am pleased to report also, Mr. Chairman, that this year the Lister Hill National Center for Biomedical Communications will be complete.

It will be completed 6 months ahead of schedule, and well under the projected budget. The availability of this facility will make it possible, for the first time, to bring together all of our technical resources, including the facilities now in Atlanta at the National Medical Audiovisual Center. We will be able to develop a coherent, well-integrated, productive research and development program in the field of medical communications and information handling.

We will complete this year the 5-year demonstration of the utility of satellite communications for support of medical care, health education, and research. We will undertake next year the evaluation of a very interesting new data base dealing with viral hepatitis, which uses mini-computer technologies for the organization and distribution of information.

TOXICOLOGY INFORMATION

The Specialized Information Service of the Library continues to provide information in the field of toxicology, and we have been working very closely with the HEW committee which coordinates all toxicology activities. We have in fact been extremely supportive, providing not only logistic support, but also intellectual support

which was crucial to the program. We are now serving not only Federal agencies, but also industry, universities, and the health practitioner.

MEDICAL LIBRARY ASSISTANCE

The extramural program of the library has been reevaluated, and a distinguished group of consultants have suggested that there remains a need for upgrading research in information technologies and for upgrading the training of health professional personnel in the utilization of computer technology to advance both health care and medical research, and thus we are giving this program the highest priority in our small grant activities.

Our request this year is for $41,431,000, the same as last year.

I would be pleased to answer any questions that you may suggest.

LIBRARY COSTS

Senator EAGLETON. I visit academic institutions from time to time, make speeches, things like that. And I know this question is sort of a generic one that goes beyond your particular statement. The thing I hear most often about, or I guess one of the things, is the library costs are eating the institutions alive. I spoke 2 months ago at the Washington University School of Law.

They have a brandnew facility. I don't recall the exact figure, but the dean was telling me just what library costs at that one law school were. It was a horrendous figure. Many, many thousands of dollars.

How are librarians, medical librarians, going to get some kind of a cost control handle on this?

Dr. CUMMINGS. The information you have been provided from law libraries is correct. Inflation is a real phenomenon. The inflation rate in the library business is more than 20 percent per year, and for the first time in my 15 years at the National Library of Medicine, we are faced with a dilemma of perhaps not having an adequate budget to acquire all of the world's medical literature. Acquisitions costs increase at double the normal inflation rate.

We are attempting to deal with this problem, Mr. Eagleton, by suggesting that libraries organize themselves in consortia, and that they in fact address the problem through cooperative acquisition and through the sharing of their resources. For example, in a community such as St. Louis, several universities might conceivably decide on sharing their acquisitions, one stressing specialization in one field, and another in another field.

Senator EAGLETON. In Amherst College, Mount Holyoke, and University of Massachusetts, I have been told they are beginning to do some sharing, which seems to be a very prudent thing to do.

The students can take courses outside of their school of residence, and they can put books on the vans and shuttle them back and forth.

Dr. CUMMINGS. In the medical library field, we have been supporting a network of regional medical libraries. In a sense we have had a favored situation, where the large universities that have the greatest medical libraries, through our subsidy, agree to share

their resources with smaller community hospital libraries and other institutions within a fairly large geographic area.

I think this may be a prototype or model for other disciplines to examine.

FOREIGN MEDICAL LITERATURE TRANSLATION

Senator EAGLETON. Do you have translators on your staff out there that do nothing but translate?

Dr. CUMMINGS. I should say we have the capability in some 40 or 45 foreign languages, and the translation that we do is done for our cataloging and indexing. But we don't announce our capability to translate, because then we would be besieged with requests to translate full articles and textbooks, and we do not have the staff to do that.

Senator EAGLETON. What does what? If there is a brilliant article written in, say, a Russian journal, or any non-English journal, Japanese, how does that brilliant article get out to American doctors?

Dr. CUMMINGS. With our own staff, and with the collaboration of institutions abroad, we try to match linguistics and scientific capability, to read the article, summarize it, and enter the correct citation for inclusion in Index Medicus and in the computer system. We have available people who know Russian, and other languages, but for some languages, like Chinese and Japanese, we have an extremely difficult task. Here we have resorted to acquiring indexing overseas from our foreign partners, who in return for using our library resources, index the literature they generate in their languages. That is a quid pro quo arrangement that is carefully monitored, and we actually set a unit price for each article they index.

Senator EAGLETON. How do you survive on a standpat budget with this 20 percent inflation rate?

Dr. CUMMINGS. Well, Congress and NIH both have been generous with the library budget. We have been able to keep abreast of inflation, until the current crunch. I am not exaggerating when I say that this is the first year when I told Dr. Fredrickson, in his recent briefings, that we might not really be able to acquire all of the literature that we think a national library should have.

We will emphasize more than ever before our exchange programs. We have just worked out an informal agreement with China. We have a Russian delegation coming to spend 2 weeks with us starting on Monday. We will try to beef up our exchange in countries that have not provided us with much literature on exchange. And we will look for other devices.

LIBRARY SERVICE USERS

Senator EAGLETON. The greatest demand for your service, I trust would come from teaching hospitals around the country?

Dr. CUMMINGS. Roughly speaking, the services we give are divided into four almost equal parts. The academic community is probably the largest user of our services.

The practitioner community, industry, and the Federal Government, each represent about a quarter of our services.

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Senator EAGLETON. Do you get frequent inquiries from doctors from small towns? Do they know about you, or know what you can do to help them?

Dr. CUMMINGS. I am sometimes disillusioned when I go to a small town and find a physician who doesn't know he has a national library, but then I'm pleased when he tells me that he can get the same service in a regional library, in Omaha, Detroit, or Seattle. So although they dont' recognize regional libraries as related to our library, they are getting the service, and that is what counts.

COPYRIGHT LAW

Senator EAGLETON. There was a new copyright law which went into effect on January 1, 1978. What effect has this law had on your library? Has there been any impact on the dissemination of information on the biomedical community because of the law?

Dr. CUMMINGS. I can deal with the latter question in somewhat quantitative terms. There has been a decline in the number of requests for photocopies of articles since the passage of the new copyright law.

Some smaller libraries, I think are frightened at the prospect of, innocently, not deliberately, making a request which will be challenged.

I would say that there has been no effect on the National Library per se, because the language of the statute places the responsibility on the borrower, rather than on the lender, so as a large lending organization, we are essentially trouble free. But the smaller institutions have new records to keep, and a number of troublesome issues are facing the small libraries.

Senator EAGLETON. We have, Doctor, some other questions, some for you, Dr. Fredrickson, and some for the various Institutes, which we will put in the record.

Well, as always, this is one of the more interesting hearings. I have looked forward to it. I'm always glad to see you, Doctor, and your associates.

QUESTIONS SUBMITTED FOR RESPONSES

[The following questions were not asked at the hearing, but were submitted to the Department for response subsequent to the hearing:]

WAMI PROJECT

Question: The WAMI Project has now been funded for several years. This, of course, involves the Washington, Alaska, Montana, and Idaho areas in developing a training and communications program for medical education. What evidence do we now have that the program has, in fact, proven to be an effective one?

Answer: The WAMI institutions demonstrated that broadband satellite communications could significantly increase resource sharing among health related research and educational institutions via courses and teleconferencing. Broadband satellite communications was found to be a highly reliable technology system for communicating health information and provides the potential for reaching very large audiences. It allowed effective communication among participants across different time zones. Experience has also shown its value in continuing education for health professionals. The extent of learning was as great with broadband satellite communications as with other electronic media and in-person instruction. The Communications Technology Satellite (CTS) experience also demonstrated that broadband two-way mode is an acceptable substitute for face-to-face communication. The costs for CTS applications varied greatly depending upon the number of participants, but under given circumstances may very well reach acceptable levels of cost/benefit ratio and thus provide means for sharing among institutions of important resources which they could not otherwise afford.

Question: What are your plans for this program in fiscal year 1980?

Answer: Our present objectives for evaluating the satellite communications as an effective mode supplementing health educational resources will terminate at the end of FY 1979. During the CTS experiments considerable technical experimentation provided important information as to the feasibility and effectiveness of this communication channel as well as providing many important technical details that contribute to making the medium more cost-effective. Experience from the present experiments with CTS following on earlier studies with the National Aeronautics and Space Administration (NASA) Applications Technology Satellite (ATS-6) program in 1974 has provided an adequate experimental period to demonstrate the capabilities of satellite communications.

BOARD OF REGENTS

Question: Last year, I understand, there was a problem in getting your Board of Regents appointed so that new grants and training programs could be funded and reviewed. I understand that Senator Magnuson had asked the White House to move as rapidly as possible on the appointment of these Regents. Are you now operating as required by law?

Answer: Following last year's Senate Appropriation Hearings, the White House submitted to the Senate the names of seven nominees to the NLM Board of Regents. The Senate confirmed these nominations on March 20, 1978, thereby enabling the Board of Regents to resume their duties which include the review of grants authorized by the Medical Library Assistance Act.

Nominations to fill the three remaining vacancies on the Board were under consideration by the Executive Branch when the Public Health Service Act was amended on November 9, 1978, to provide for appointment of the NLM Board of Regents by the Secretary, DHEW, rather than the President. The Secretary made the remaining appointments within three weeks and we now have a full complement of ten appointed Regents.

BRAIN INFORMATION SERVICE

Question: Last year, the Committee directed you to do a study of the Brain Information Service which had been funded by the Neurology Institute. What conclusions did this study come to, and what action is necessary to be taken?

Answer: After discussions between senior staff of NLM and the National Institute of Neurological and Communicative Disorders and Stroke, a site visit to the Brain Information Service (BIS) was conducted in December 1978 by a team consisting of the following:

Dr. Harold M. Schoolman, Deputy Director for Research and Education, NLM;

Dr. W. Watson Alberts, Health Science Administrator, NINCDS;

Mr. Melvin Day, Director, National Technical Information Service, Department of Commerce;

Dr. David N. Cohen, Professor of Physiology, University of Virginia;

Dr. William D. Willis, Jr., Director, Marine Biomedical Institute, Galveston, Texas.

The latter two members were selected to represent the interests of the professional community served by the BIS. A copy of the full report has been provided to the Senate Appropriations Committee. The following is a summary of conclusions and recommendations.

The responsibility for specialized information services such as the BIS should remain in the categorical research institutes. The scope of such services should be determined by the institute in consultation with the appropriate professional community. The effort should be concentrated on that area which is generally considered to have the greatest scientific activity and current progress. This effort must therefore be adjusted from time to time in keeping with the changing nature of activity in the field. A balance between information synthesis and bibliographic activities should be sought.

The National Library of Medicine should not handle specialized information requirements through its facilities. However, the resources of NLM should be fully utilized in creating the services and products of specialized information services such as BIS.

NATIONAL MEDICAL AUDIOVISUAL CENTER
NMAC

Question: In March 1978, the General Accounting Office (GAO) issued a report on its evaluation of the management and efficient use of Federal funds at NMAC, which is part of the National Library of Medicine. GAO reported that NMAC was: (1) incurring excessive costs in its contract program; (2) lax in enforcing contract deadlines; (3) receiving poor quality work from its contractors; (4) not fully or productively using its personnel and equipment; and (5) not evaluating how effectively it was accomplishing its mission. GAO made several recommendations for improving NMAC's management and use of resources, including that no additional employees be hired or equipment purchased by NMAC until it had an acceptable strategy and specific plans and objectives for accomplishing its mission and that appropriate action be taken to see that NMAC had only that equipment and those personnel essential for accomplishing its mission. What actions has HEW taken--in response to GAO's recommendations or otherwise--to correct the problems at NMAC?

Answer: In late 1979, upon completion of the construction of the Lister Hill Center communications facility, NMAC personnel, equipment and activities will be relocated from Atlanta to the new building in Bethesda. NMAC will be integrated with the LHC to form a single organization with a common mission. The existing missions of these two organizations and their relationships to the needs of the biomedical community have been evaluated in-depth by the NLM Board of Regents. The report of this evaluation has been used by the staff to reassess the existing programs and develop the new mission and organization structure for the combined LHC/NMAC.

As vacancies have occurred in NMAC the positions have been reviewed by senior NLM staff for possible reassignment to the Lister Hill Center. The number of NMAC employees has been reduced in the last year from 91 to 83. In addition this organization has undergone a change in directors during the last month. We continue to make plans for the reorganization and relocation of the NMAC staff and functions.

PRIORITIES

Question: Dr. Cummings, what do you consider to be the most important program within the National Library in 1980?

Answer: During periods of severe budget constraints and with library costs inflating at a rate of 20 percent per year the National Library of Medicine must protect its basic library and information services. These unique mandated services we perform for the entire biomedical community must be considered our highest priority activity. We are hopeful, nevertheless, to adequately support our research and development efforts in computer and communication technologies particularly now that the specialized facilities of the new Lister Hill Center Building will soon be available. We must be able to exploit existing and newly emerging technologies if we are to effectively improve information services to the health community.

SUBCOMMITTEE RECESS

Senator EAGLETON. The subcommittee will stand in recess until 10 a.m., Tuesday, when we will have the Alcohol, Drug Abuse, and Mental Health Administration, et cetera.

[Whereupon, at 4 p.m., Thursday, March 1, the subcommittee was recessed, to reconvene at 10 a.m., Tuesday, March 6.]

DEPARTMENT OF LABOR AND HEALTH, EDUCATION, AND WELFARE AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 1980

MONDAY, MARCH 5, 1979

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
Washington, D.C.

The subcommittee met at 1:10 p.m., in room S–128, the Capitol, Hon. Harrison H. Schmitt presiding.

Present: Senators Schmitt and Schweiker.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION

STATEMENT OF GERALD L. KLERMAN, ADMINISTRATOR

ACCOMPANIED BY:

LORAN D. ARCHER, ACTING DIRECTOR, NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM

KARST J. BESTEMAN, ACTING DIRECTOR, NATIONAL INSTITUTE ON DRUG ABUSE

HERBERT PARDES, DIRECTOR, NATIONAL INSTITUTE OF MENTAL HEALTH

KENT L. AUGUSTSON, FINANCIAL MANAGEMENT OFFICER, ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION

BRUCE S. WOLFF, DEPUTY ASSISTANT SECRETRY FOR LEGISLATION DESIGNATE

WILFORD J. FORBUSH, DEPUTY ASSISTANT SECRETARY, BUDGET

BUDGET REQUEST

Senator SCHMITT. The subcommittee will come to order.

This afternoon we will hear testimony on the 1980 budget—that is fiscal 1980, I presume—request of $916.5 million for the Alcohol, Drug Abuse, and Mental Health Administration, commonly known as ADAMHA.

ADAMHA is the arm of the Public Health Service responsible for research, training, and delivery of services in the areas of alcohol, drug abuse, and mental health.

Many of the ADAMHA proposed increases in fiscal year 1980 reflect recommendations of the President's Commission on Mental Health.

Dr. Klerman, the Administrator of the Alcohol, Drug Abuse, and Mental Health Administration, is with us today.

Doctor, I am very happy to make your acquaintance at this time, and I would like you to introduce for the record your associates, and summarize your opening statement, if you please.

PREPARED STATEMENT

The entire statement will be, as usual, included in the record, and we will have time, then, for some questions.

[The statement follows:]

Statement of Gerald L. Klerman

Mr. Chairman and Members of the Committee:

It is a pleasure to make my second appearance before this Committee to discuss the programs and plans of the Alcohol, Drug Abuse, and Mental Health Administration for the coming fiscal year. The Director and Acting Directors of the three Institutes that comprise our agency are here with me.

The encouraging progress that has been made in our three fields leads us to believe that Federal programs can continue to help solve many alcohol, drug abuse, and mental health related problems. The budget proposal which I will discuss with you represents carefully drawn plans for the next steps.

EXTENT OF THE PROBLEM

The Committee is well aware of the tremendous scope of alcohol, drug abuse, and mental health problems in our society: There are an estimated 9-10 million problem drinkers in the adult population, 25 to 35 percent of them women. In addition, we now estimate that 3.3 million youths are having problems connected with drinking.

The number of heroin addicts in the U.S. is still substantial, although decreasing. Marihuana use continues to grow, with as many as 11 percent of high school seniors--a most vulnerable age group-- now reporting daily use.

Surveys for the President's Commission on Mental Health found that fifteen percent of our population needs some form of mental health care in the course of a year. Two million Americans are diagnosed as schizophrenic, and 10-14 million suffer from depressive disorders.

PROGRESS BEING MADE

I am pleased we can take note of progress against these problems on a number of fronts. To mention only brief examples: The death rate in this country from cirrhosis of the liver has shown a decrease for the first time in more than 50 years. A 20 percent drop in the number of heroin addicts also has occurred since 1975.

We have recently identified opiate receptor sites and natural opiate compounds in the brain. Dramatic strides have been made in recent years as well in understanding the important role of neurotransmitters in the brain. Psychoactive drugs have shortened treatment for many mental patients, and helped cut mental hospital populations in half.

1980 BUDGET EMPHASES

Mr. Chairman, the 1980 budget proposal before the Committee emphasizes implementation of the recommendations of the President's Commission on Mental Health for improving and expanding the delivery of mental health care to underserved segments of our population. It also incorporates new high priority Departmental initiatives aimed at curtailing alcohol problems among special target groups. I would like to describe each of these proposed emphases for 1980 in the context of the agency's budget requests for needed research, training, service and prevention activities in each of our three Institutes.

RESEARCH ACTIVITIES

To begin with research, the overall budget request for Institute programs is $38 million above the 1979 level. This major increase will provide both for a strengthening of our overall research base, and for new initiatives in areas highlighted by the President's Commission. The recommended increase accords with the agency's longstanding priority on research.

Our belief in the paramount importance of a high quality research program is also reflected in our recent reorganization of the peer review of research applications to separate review for scientific merit from management of awards. Review activities will now be centralized in the Office of the Director of each Institute.

The overall boost for research in ADAMHA includes a 20 percent increase for investigations by the National Institute of Mental Health. Studies will include an intensified effort to gather reliable data on the incidence of mental health problems in communities and the Nation as a whole, and on utilization of mental health services. There is a clear need for better data about the extent of mental disorders; how and where they are treated; and at what cost. A closely related area which will be emphasized is treatment assessment research--to scientifically determine the effectiveness of various treatment approaches.

Additional resources also will be assigned to studies of the major mental illnesses such as schizophrenia and depression, and to advancing understanding of the basic biological and psychological processes involved in these tragic disabilities.

In the mental health intramural research laboratories, staff scientists will expand their key investigations of childhood depression and hyperactivity, as well as brain chemistry studies. The latter area will include further development of highly promising work on the endorphins, whose recent discovery has striking implications for treatment of both mental illness and drug addiction.

Further advances in understanding of the endorphins and their receptors in the brain will also be sought through the basic and applied research programs of the National Institute on Drug Abuse, which receive an increase of nearly $8 million in the 1980 budget. Other priority areas for drug abuse research include nicotine dependence, the biologic conditions predisposing persons to abuse drugs, and further testing of treatment drugs such as the narcotic antagonists.

The budget request for alcoholism research is $25 million, a $3 million boost over the 1979 budget level. This increase reflects both the special alcoholism initiatives of the Department and the recommendations of the President's Commission on Mental Health. It will allow us, among other research targets, to learn more about the causes and effects of alcohol abuse among women and youth and to develop additional knowledge about the fetal alcohol syndrome.

RESEARCH ON PREVENTION

Research dollars are designated in the budgets of all three Institutes to develop information which will expand our ability to prevent alcohol, drug abuse and mental health problems before they occur, thereby eventually reducing the number of cases.

To augment the agency's prevention efforts, establishment of a Primary Prevention Center within the National Institute of Mental Health is proposed in 1980 and additional funds will be used to stimulate

epidemiological, biomedical, behavioral, and clinical studies relating to prevention. The prevention strategy of NIAAA includes a major educational program to inform women of childbearing age about the risks of fetal alcohol syndrome inherent in drinking while pregnant.

IMPLEMENTING PCMH RECOMMENDATIONS

Turning to services, the 1980 budget and legislative program takes the first steps in implementing the recommendation of the President's Commission that this country redress the present deficiencies in our national system for providing mental health care.

As the Committee is aware, the President established the Commission to review the mental health needs of the Nation and to make recommendations concerning the role of the various levels of Government, and the amount of financial support needed, to resolve the problems identified. The Commission concluded that children, the aged, minorities, the chronically mentally ill, and persons in certain geographic areas are the most underserved by the present system.

The President's budget before the Committee today shows a decrease for the current mental health services program, and new community mental health legislation is being developed for later transmittal which will add $99,100,000 for a new program of greater flexibility and scope. We are also proposing to utilize $30.5 million provided under the continuing resolution for community mental health centers to initiate these efforts in 1979. The new approach will encourage States to improve the coordination of mental health services, especially with regard to the chronically mentally ill, and will provide for more specialized local services grants.

ALCOHOL INITIATIVES

As I have indicated earlier, the 1980 budget also proposes new service initiatives to combat alcohol problems. Six areas have been identified for additional funding: alcohol problems among women, among youth, the fetal alcohol syndrome, occupational alcohol programs, the HEW employee assistance programs, and alcohol problems related to domestic violence. Of $35.5 million requested for these Departmental initiatives, $22.5 million would go for new projects. A specific example is the urgently needed development of additional specialized treatment programs to provide a comprehensive range of services to youths, including alcohol detoxification, group and individual counseling, referral to health and social agencies, vocational counseling and job placement, and legal assistance services.

REDIRECTION OF TRAINING

A constructive redirection consistent with the training priorities recommended by the President's Commission is now fully underway in our mental health manpower program--totally shifting from the traditional focus on developing the core professions to a strategy more directly addressing maldistribution problems and meeting the needs of unserved and underserved populations. Initiated to some degree in previous years, we propose to strengthen this new channelling of funds and to make the redirection more explicit in 1980. We are also seeking authority to require a service payback from students in return for the support they receive for their training.

PROPOSED STATE GRANT PROGRAM

The budget proposal before the Committee does not contain a request for drug abuse and alcohol formula grants or for the existing mental

health State grant program. A legislative proposal being developed for later transmittal to the Congress will incorporate funding for these into a consolidated State alcohol, drug abuse, and mental health grant program. The funding request will be $99 million, which represents 90 percent of the combined current level for these programs.

.1979 SUPPLEMENTAL REQUEST

At this time we are also presenting a $4,118,000 supplemental budget request for 1979 for General Mental Health programs. An additional $1,564,000 is requested for the research program on rape prevention and control in light of the increasing incidence of rape within the Nation and an additional $2,554,000 is requested for the research training program to help insure the existence of an adequate number of qualified investigators in mental health research fields.

SUMMARY

Mr. Chairman, in conclusion, the document before you requests a total of $916,510,000 for Alcohol, Drug Abuse, and Mental Health in 1980. Inclusion of the two legislative proposals to be transmitted later--i.e., for a new community mental health services program, and for a State grant program--will increase that total to $1,114,610,000. This is an increase of $84,962,000 above the 1979 level, including increases of $38 million for research and $46 million for community project grants and contracts, and a decrease of $6 million for training programs.

Mr. Chairman, I will be pleased to answer any questions you or other members of the Committee may have.

INTRODUCTION OF ASSOCIATES

Dr. KLERMAN. I am very pleased to be here to represent the agency and to describe our program. I am accompanied by the directors or acting directors of the three institutes which comprise the agency.

Dr. Herbert Pardes is the Director of the National Institute of Health on my right.

Mr. Loran Archer, who is the Acting Director of the National Institute on Alcohol Abuse and Alcoholism, is on my left.

And further down is Mr. Karst Besteman, who is the Acting Director of the National Institute on Drug Abuse.

There are other members of the staff from the Budget and Planning Departments. We are also accompanied by Mr. Forbush and Mr. Wolff of the Department of HEW.

I will make a very brief statement so as to allow time for questions.

BUDGET HIGHLIGHTS

As you noted in your opening remarks, we have passed through a period where there has been a searching review of Federal policy with regard to mental health.

Soon after taking office, Mr. Carter appointed the President's Commission on Mental Health, which delivered its report to the President in April of 1978.

The majority of the recommendations in that Commission report bear upon the programs of HEW in general, and of this agency in particular.

The Department has undertaken a thorough review of these recommendations, as well as other policy issues relevant to mental health, and this budget request represents a major attempt to implement the many recommendations of the Commission, particularly as they apply to research, to clinical training, to the development of programs of prevention, and to redirection of community mental health services programs.

In addition, the Secretary, Mr. Califano, undertook a review of the HEW policies and programs in alcohol abuse and alcoholism beginning about a year and a half ago, and some of the initiatives that came out of that departmental review are also reflected in this budget.

For the most part, the budget request is to continue programs as they have been in the past because of the constraints of the budgetary situation. However, priority has been given by the Department and the administration to developing new initiatives in the two areas that I have identified—those coming from the President's Commission on Mental Health, and also from the Department's initiative on alcohol abuse and alcoholism.

In addition, we are moving forward——

ADAMHA INSTITUTES

Senator SCHMITT. Doctor, could I interrupt right there?

Would you just state as simply as possible why the three areas of alcohol, drug abuse, and mental health are considered within HEW—and maybe this is partly the responsibility of the Congress—but as a managerially coherent unit?

Dr. KLERMAN. That is a reflection of a congressional decision a number of years ago. Originally, alcoholism programs and drug abuse programs were subsumed under the National Institute of Mental Health. The Congress, a number of years ago, established the alcoholism field and the drug abuse field as worthy of separate Institute functions.

What they share in common is that the manner in which persons afflicted with these illnesses present themselves to society gets the attention of social agencies as well as the medical community.

Also, the brain is the part of the body that is most often involved in the genesis of these behaviors. The brain and society are common areas of causation and treatment for these three groups of disorders.

These three groups of disorders also share an administrative similarity. Unlike the other National Institutes such as the Heart Institute or the Cancer Institute, the three Institutes that comprise our program have a multiplicity of statutorily defined missions.

All three of the Institutes represented today conduct research both through intramural programs, and extramural programs; they also are involved in the support of service programs through States or local communities, in the development of prevention activities, and in the augmentation of training of clinical research personnel.

The Institutes under the administrative support of NIH are almost exclusively involved in research. The services and preventive functions of those disorders are supported by other agencies of the Public Health Service.

Senator SCHMITT. Thank you.

Dr. KLERMAN. The last comment I would make is that, in addition to the two areas of special interest for this year that I have identified—namely, those that come from the President's Commission on Mental Health, and the Secretary's concern for these special problems of alcohol abuse and alcoholism—we are continuing the special activities with St. Elizabeths Hospital to reestablish accreditation there. That is also part of this budget.

I think I will stop at that point. Any specific comments you might have I would be glad to try to answer in general and, if they go to either of the Institutes, the Directors are prepared to go into detail.

ADAMHA PRIORITIES

Senator SCHMITT. Please feel free to ask your Institute Directors for their assistance.

Dr. Klerman, ADAMHA is now a billion dollar program almost. It is only slightly behind Congress. And I presume we, in some people's minds, might be included in the 10 percent that I just noted as suffering some kind of mental health disorder.

You have been at its head for 2 years. It is an appropriate title, since you are the brain institute.

Now that you have this experience, what do you consider to be the highest priority program areas? And be as specific as you can.

Dr. KLERMAN. We in the agency give highest priority to research, although that represents about 20 percent of the total budget. It is the Federal contribution to research that is absolutely essential. Research could not continue without the Federal input.

The Federal funds represent about 90 percent of the total national efforts in these fields. So although, again, the research budgets of the three Institutes comprise about 20 percent of our total budget—which, as you say, is about to cross the billion-dollar mark—these funds support the research capability for alcoholism, drug abuse, and mental health.

Our second priority is to restructure the health care delivery system to make it more accessible, more responsive, and more cost effective. And in the fields we represent, our efforts are to increase simultaneously the capacity of the country to treat disorders of alcoholism, drug abuse, and mental illness while integrating and linking these services to the general health care system.

5-PERCENT CUT

Senator SCHMITT. If you were forced to make a 5-percent reduction in your office in all three Institutes, where would you take that money from?

Dr. KLERMAN. That is a very difficult question. We have been through a period where inflation and prior appropriation levels have rendered us less capable.

I think we would want to reflect upon this in each of the Institutes since they might each react differently. I would personally feel that the maintenance of the research capability would be the highest priority, and I would be reluctant to cut into that, especially since it represents only 20 percent of the budget.

I think it is in the area of service programs in the States and local communities which comprise about 65 percent of the total appropriations that, if we were forced to, we would have to look to for cuts.

But the priorities are different for different fields, and the Institute Directors might have comments to make.

Senator SCHMITT. Does anybody care to make a comment?

Dr. PARDES. I would just endorse Dr. Klerman's statement about the history of support for mental health programs through the Institute, and say that a suggestion of a cut at this particular time in mental health would come—would present us a very serious problem. And I particularly emphasize the history of relatively slower growth in support for mental health programs over the last number of years, as compared to some areas of health.

I would also make the point about the fact that the support of mental health problems in this country, in comparison with the support for other health programs, is proportionately low.

Mr. ARCHER. I would be reluctant to look at a question of a 5-percent decrease.

Senator SCHMITT. I am reluctant to ask it, but unfortunately neither one of us has an option.

Mr. ARCHER. It would be false economy in the fact that we have already been looking at the question of how we can develop lower costs for delivering services.

And we have come up with some very innovative ways, and the effects are already being costed out within the health care system, through reducing expensive hospital care. And if you do not provide lower cost alternatives such as we have pioneered, you would probably end up in the next several years spending more than 5 percent.

I think we can show, through our own cost efficiency and effectiveness of treatment, that we have saved and have been saving more than the 5 percent by actually moving from higher cost to lower cost methods of delivering care.

We, as I said, have looked at the cost of health care delivery systems. The costs as a result of alcohol abuse end up very heavily in chronic disease, in burns and injuries, and I think it would be very difficult, and perhaps a false economy, to cut the budget at this particular time.

Dr. KLERMAN. Mr. Besteman, I think, could comment for the drug abuse field.

Mr. BESTEMAN. My comments would be in the line of what has been said, but I think you have to get to a point of what should be the Federal role in drug abuse.

If you start to exercise the option for further cuts into the Institute programs, I think you have to then see what your tradeoff is in terms of the impairment of that Federal role and how that will play out over time.

I think the budget being presented is a conservative, carefully-put-together budget. It protects the core of the Federal role and maintains a function that is necessary for the country and for the field. It does not go much beyond that.

COST BENEFIT OF RESEARCH

Senator SCHMITT. Your difficulty is the difficulty that I have sensed in the Congress, as well as in the administration. And that is one of clearly and persuasively justifying deferred benefits to a certain cost, and research is almost invariably an investment that has deferred benefits.

And unfortunately, budgets come once a year. And that is why these questions appear, and that is why they are treated by the Congress.

Hopefully, over the next few years, I will do everything I can to influence it to start to draw a much more distinct distinction between the deferred benefits of research, whether it is in mental health, or engineering R. & D., or what have you, over their immediate costs.

You have to look at that. You can't do an annual cost/benefit study on research, and particularly in the health problems.

How do you feel that your budget is clearly defensible, that research portion of that budget, in that you are working on lower cost treatment or prevention of problems, rather than the high cost of treatment of existing problems?

Am I clear in my question?

Dr. KLERMAN. Yes, the point is well taken.

Senator SCHMITT. Polio is probably one of the best examples of where research eliminated a problem. Hopefully it will stay eliminated.

Dr. KLERMAN. I think we can point to areas of substantial progress in the health fields represented here that indicate payoff.

For example, the death rate from cirrhosis of the liver, which is one of the main consequences of alcoholism, has been down for 4 or 5 consecutive years for the first time in some 30 or 40 years. Now, that is a complicated factor. Part of it is better diagnosis, and better treatment, and a reduction of the stigma attached to alcoholism that comes from the very creation of NIAAA. Also the research programs that NIAAA have supported, which indicate that alcohol is a toxic agent on the liver, independent of poor nutrition, have played a significant role.

Similarly, in the mental health field, we could go into great detail. There have been very significant reductions in the use of hospitalization, and a shift from hospitalization—which is the most expensive and compulsive dependency producing part of the health care system—to community alternatives.

This is reflected in the fact that in 1955 there were half a million people hospitalized in institutions and it was increasing about 10 percent per decade. The country would have had to spend billions of dollars to increase the number of hospital beds.

Now the situation is completely reversed. The bed capacity is going down. We have shifted to less expensive forms of ambulatory care.

I would submit that that is partially the result of new drugs, some of which came from Europe, and better knowledge of how the brain works, but also our ability to change the social environment to allow for treatment outside of those hospitals.

COST-BENEFITS

Senator SCHMITT. Doctor, I hope that you and your colleagues would submit for our record a few of the best examples that you have, if they are not in your testimony—and I am sorry, I have not read that—examples of how there has been a cost-benefit demonstration.

And I know it is almost impossible to estimate what those benefits are, but we generally have to take them on faith because we have so many examples that far exceed the cost of the original effort.

So if you could supply us with that?

Dr. KLERMAN. We would be delighted to.

[The information follows:]

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RESEARCH WITH DEMONSTRATED COST BENEFIT IMPLICATIONS

Each of the three Institutes within ADAMHA has sponsored projects which have or may lead to subsequent cost savings. Following are some specific examples.

Due to increasing attention to the severly disabling problems encountered by families caring for behaviorally disordered children, NIMH implemented a controlled study to assess treatment outcomes for children assigned to either hospital or a structured community treatment regimen. Evaluation indicated that whereas equivalent overall adjustment gains were made by the children in both settings, hospital care proved to be five times more expensive than the community setting. This provides evidence that those children remanded to inpatient treatment may be as effectively treated in a community setting at less cost using one particular treatment model.

Over the years, NIMH has been developing alternative treatment approaches for delinquent youth. One of these is a Teaching-Family Group Home model in which a specially trained couple lives with and assists delinquent youths. The annual cost per youth in this model was found to be about $6,600 as compared with $10,000 for other types of group treatment homes, approximately one-third less costly. Currently, some 150 community based group homes are using this model, supported by state and private funding sources.

NIDA sponsored studies have shown that the methodologies used for the treatment of opiate addiction are effective and that for every one dollar spent on treatment, thirteen dollars are saved by virtue of decreased use of medical facilities and the criminal justice system, as well as a reduction in general social costs.

Another NIDA study examined the effectiveness of inpatient versus outpatient methadone detoxification and indicated that the average detoxification procedure could be just as efficiently and effectively conducted on an outpatient basis as on an inpatient basis. The annual cost of maintaining a hospital bed for inpatient detoxification is estimated to be $40,000 ($110/day). The annual cost of maintaining an outpatient detoxification slot in a clinic is $2,000. The length of treatment is a maximum of 21 days, regardless of whether the detoxification occurs in an inpatient or an outpatient treatment setting. Therefore, there is an annual savings of $38,000 per detoxification slot. More than 475 inpatient slots were eliminated and the resulting $18,000,000 were used to fund other treatment services. This research project resulted in the reallocation of treatment dollars which were then able to provide services to an additional 18,000 clients without increasing the total treatment budget.

Due to NIAAA funding, better screening techniques have been developed in the diagnosis of alcoholism and its related physical problems. One special development has been the application of computerized tomography scanner techniques in the diagnosis of brain damage in alcoholic individuals. This improved diagnostic technique makes possible early therapeutic interventions during the reversible phase of the neuropathological process, a step in the prevention of alcohol-induced chronic brain damage and the concomitant costs to society.

NIAAA studies have shown the relationship between fetal pathologies and excessive alcohol consumption by mothers during pregnancy, and have led to increasing prevention efforts. The prevention of these pathologies results in major savings both in terms of the monetary costs of treating and maintaining patients and the human costs of suffering.

OPERATIONAL COMMUNITY MENTAL HEALTH CENTERS

Senator SCHMITT. I just noticed, I had all the acronyms put down here, and one of the natural laws of Washington that I have discovered since I came back here as a scientist, and now in the Congress, is that agencies tend to take on the characteristics of their acronym.

I have not quite figured out what the characteristics of these acronyms are, but I will work on it.

"ADAMHA" may mean that you are adamant about particular issues. At any rate, we will leave that.

With respect to community mental health centers—and if there is time at the end maybe we can get back to research—but in 1977 there were 592 community centers in operation. In 1978, there were 625 centers.

How many are operational now?

Dr. KLERMAN. I think that is best answered by Dr. Pardes, since it is a program of NIMH.

Dr. PARDES. I believe the number expected to be in operation is 678 in 1979.

CMHC IMPACT

Senator SCHMITT. What kind of impact do these centers have? And is it possible to measure that impact in a quantitative way?

Dr. PARDES. I think that the community mental health centers have had a very substantial impact. They cover nearly half of the U.S population and actually treat 2.7 million patients each year. One of the examples that Dr. Klerman gave, for example, is the question of the locus of treatment for people with mental health problems.

There have been a number of factors which have contributed to that switching locus. And by that I mean, for example, the difference between numbers of inpatient episodes as opposed to numbers of outpatient episodes.

If you look at the overall collection of mental health——

Senator SCHMITT. Would you explain that?

Dr. PARDES. In other words, the number of people who received their services in an inpatient setting, as opposed to an outpatient treatment.

Senator SCHMITT. And you consider these community centers as outpatient?

Dr. PARDES. Well, they may have a whole range of services, but by their existence and their rendering of such services, they have made a contribution to altering the balance between inpatient and outpatient.

If you go back about 20 years, the proportion was about 3 inpatient episodes to 1 outpatient episode. That has in fact become inverted currently. In other words, there has been a substantial increase in outpatient work. That should be much more economical, and also it is intended to prevent larger numbers of hospitalizations.

So there might be one rather explicit example of the way community mental health centers have had an impact.

They have also brought to a larger segment of the public mental health services which previously were not available.

Senator SCHMITT. What generally has the increase in funds over the past 2 years been used for?

Dr. PARDES. The increase in funds? It has been an increased number of centers——

Dr. SHARFSTEIN. An increased number of centers, additional patients treated, and also an increased number of services in the centers that were funded before.

HOME MENTAL HEALTH CARE

Senator SCHMITT. Let me also ask you, either for the record or very quickly: Do you find that these centers have helped in providing home mental health care? That is a major movement now, I think, among other aspects of health care, to try to maximize the amount of home health treatment that is possible because of costs.

Dr. PARDES. You're making the point about home health treatment, as far as health treatment——

Senator SCHMITT. Or either in centers. Does this act as a transition?

Dr. PARDES. What I said before, I think, addressed that question. In other words, they would not have to go out of the home into inpatient centers by virtue of the availability of the community mental health centers.

There is also, however, a development of a larger range of alternative settings in which mental health services can be delivered, again attempting to reduce the cost of the most expensive inpatient treatment.

Senator SCHMITT. You mean more disseminated?

Dr. PARDES. To place larger segments of the mental health treatment function in other than hospital settings.

Senator SCHMITT. And also, broader geographical distribution?

Dr. PARDES. Yes; broader geographical distribution, as well.

SERVICES TO THE ELDERLY

Senator SCHMITT. Is medicare paying for any of these services?

Dr. PARDES. Again, I guess when you say home health services, do you mean services delivered at a person's own house?

Senator SCHMITT. Yes. Or just generally outpatient care.

Dr. PARDES. Let me just comment about the medicare reimbursement of mental health services, generally. For example, the limitation for medicare outpatient services is $250. And there is a coinsurance requirement of 50 percent in contrast to the coinsurance requirement in general health of only 20 percent.

That would mean that, for example, the elderly who required mental health care would have to pay half of the costs and in addition would have a limit on how much outpatient care they could seek. The administration, recognizing this problem, is suggesting changes in medicare reimbursement in this year in order to make the benefits more appropriate to the needs.

Dr. KLERMAN. I think if I could amplify, Senator. With regard to the elderly, they often are the most in need of home health care services. They have not been as quick to respond to the availability

of community mental health center programs as their need would indicate, and they are over-represented, unfortunately, in the institutional population, particularly in nursing homes.

And about 5 percent of people over 65 are in institutions of one sort or another. We feel that a moderate percentage of those individuals who have psychiatric and mental disorders that are elderly could be treated outside these institutions in their own homes through a combination of Meals on Wheels, home visits by nurses, social work or day centers.

But some of the reimbursements in the medicare and medicaid provisions actually inadvertently reinforce the use of expensive care and hinder the availability of ambulatory and home treatment facilities. However, I understand we are presenting before the Finance Committee a proposal to liberalize outpatient benefits from $250 to $750.

That requires a legislative change and, as I understand it, goes before the Senate Finance Committee. In addition, we have a very good working relationship with the National Institute on Aging and have undertaken a number of joint projects with them to seek ways of reducing the extent to which the elderly are in nursing homes.

LINKAGE WITH OTHER SERVICE AGENCIES

Senator SCHMITT. But you are attempting to have your community centers cooperate with other community centers that are serving particularly the elderly?

Dr. KLERMAN. Yes, sir. I would say one of the most successful recent programs has been a series of linkage grants between mental health centers and rural health centers, neighborhood health centers.

SERVICES TO LONG-LIVED CITIZENS

Senator SCHMITT. What about the centers that serve what I much prefer to call long-lived citizens rather than elderly? The Soviets use that term, and that's one of the few things that I think that they have hit on. Just day centers, you mentioned that a moment ago.

Dr. KLERMAN. In the appropriation request, which requires new legislation, we are putting aside $15 million for linkage grants to link mental health centers with other health care delivery types of facilities.

Senator SCHMITT. But there are many of these facilities that are just merely places of recreation.

Dr. KLERMAN. We have looked for those that actually deliver health care.

Senator SCHMITT. But that is health care, particularly mental health care.

Dr. PARDES. One of the key programs in the community mental health centers program, Senator, is a program of interaction with other agencies within the community, recognizing the fact that mental health problems may come up in a variety of settings, be they nursing homes, be they schools, et cetera.

The community's mental health centers have what they call a consultation and education program, which is to try to help these other agencies in being alert to mental health problems and also to

make it clear to other agencies that the community mental health centers are available.

COST BENEFIT OF SERVICES

Senator SCHMITT. Do you make any attempt to show—can you show a cost-benefit analysis on how the increase in funds is a particular incremental increase that contributes in terms of dollars to either the local community or to the Federal budget?

Dr. PARDES. Could you repeat that?

Senator SCHMITT. The cost-benefit study, basically, we give you x number of dollars. How does that play out over a period of time for this kind of a program?

Dr. PARDES. Well, I guess I was trying to indicate there are several different ways one could approach that. I will try to illustrate——

Senator SCHMITT. Well, I'm just asking you just the factual question: Do you try to do it quantitatively?

Dr. PARDES. Yes.

We are concerned about showing by what means the investment in mental health services and mental health programs have direct benefit. One of the additional——

Senator SCHMITT. Direct economic benefit in addition to the social benefit?

Dr. PARDES. Let me illustrate another avenue of approach that we have tried to take, and that is the question of the offset between mental health benefits and general health services needs. There have been a number of studies which suggest that if one appropriately has mental services within a defined community or a defined group of people, the use of general health services is reduced.

Now, if one thinks about it, if one thinks about a sample situation—a person may have psychological difficulties manifested by physical symptoms and may go to any number of general health facilities for attention; when going for appropriate mental health treatment, the general physical or the general health services might be reduced.

There are people who go from clinic to clinic to clinic trying to find out what the problem is, and the problem is really more of a psychiatric one. Finally, after having been sent to or referred to a mental health setting, the need for other general health services is often reduced.

Dr. KLERMAN. We have very good benefit-cost studies in alcoholism, as well as mental health and drug abuse which we can provide you, if you wish, for the record. As to quantitative return, there is a return between $4 and $8 in increased productivity and reduced cost for every $1 expended in the treatment program.

ALCOHOL BENEFIT-COST STUDIES

Mr. ARCHER. Perhaps the simplest and most straightforward example is a group of 2,000 patients which we followed. We looked rather simply at some of the hard figures which we could validate. That is, we looked at their income, the number of dependents, and the standard tax tables and found the amount of tax they were paying and followed them up after treatment and found out the

increased tax they were paying. We found out that that increased tax just of those who were successful was enough to pay the entire cost of the program over a 3-year period.

Senator SCHMITT. Well, I think a summary of that information would be very useful to us in our evaluation.

[The information follows:]

COST BENEFITS OF ALCOHOLISM SERVICES

The enormous cost to society of alcohol-related accidents, disease and death, $42 billion each year, strongly suggests the need to allocate funds for alcoholism and alcohol abuse especially to the populations which are historically underserved and where we can predict the greatest savings and prevent unnecessary expenditures. A summary list of the cost benefits is as follows:

1. The Cost-Benefit Analysis study of NIAAA Alcoholism Treatment Centers (ATC's) showed:
   - A return to the National economy of about three dollars for each dollar expended for treatment.
   - Client benefits over 10 years were estimated to be nearly six dollars for every dollar of program costs.
   - Benefits resulted from reduced health care costs, higher earnings, decreased criminal justice costs, and motor vehicle accidents prevented.
2. Client treatment costs have declined since 1972 as shown in the National Alcoholism Program Information System (NAPIS) Report on NIAAA-funded projects for 1977 and various special internal studies due to:
   - Use of less expensive outpatient services; and
   - Greater use of non-degree staff by treatment units.
3. A study of three Health Maintenance Organizations (HMO's) in California by Group Health Association of Amercia showed:
   - HMO's which have initiated comprehensive alcoholism treatment programs indicate that there is a reduction in total health care use for the individual, as well as his family, when alcoholism is identified and treated appropriately.
   - Reduction of 31 percent in utilization of total health care after treatment.
   - 57 percent reduction reported in health care use by family members of the alcoholic person as well.

FUNDS FOR NEW CENTER IN 1979

Senator SCHMITT. Senator Schweiker.

Senator SCHWEIKER. Thank you.

The area I'm interested in is the $30 million for new community mental health centers that has not been utilized. And my question is: Why hasn't it been utilized, and what are you planning to do with it?

Dr. KLERMAN. I think Dr. Pardes is prepared to respond to that.

Dr. PARDES. Senator, it is the administration's intention to introduce a major new piece of legislation on mental health services, and it is our intention to utilize that $30 million to spend on programs that would fit within that new piece of legislation. The legislation captures much of the thinking of the Presidential Commission on Mental Health which we view as one of the most updated appraisals of the needs of the mental health system, and as a result, we would want money spent in conformity with what might be the most up to date appraisal possible.

Senator SCHWEIKER. One of the followups would be: Why didn't you request a formal deferral in accordance with the committee procedure at this point?

Dr. KLERMAN. We do not intend to let those funds lapse within the fiscal year. If it does not appear that the new legislation will be in place in sufficient time, we will release those funds for payment

of grant applications previously approved under legislation authorized by congressional action taken last year on the Community Mental Health Centers Extension Act.

Dr. PARDES. Let me make just one additional comment to Dr. Klerman's statement, and that is that those moneys would be spent as he said in conformity with existing legislation, but keeping in mind the Presidential Commission on Mental Health priorities captured within the proposed new systems act.

Senator SCHMITT. Is your counsel here? Do you have a counsel, legal counsel?

Well, go ahead, Senator.

APPLICABILITY OF IMPOUNDMENT ACT

Senator SCHWEIKER. On this aspect, if you don't spend it within 30 days you're supposed to send us a deferral based on the Impoundment Act, and you are obviously not complying with that.

Mr. WOLFF. Sir, I think it depends on what the program is. This program is generally obligating its funds in the fiscal year, and therefore deferral is not apparent in this case. I'm talking about the new awards, the continuations coming up as they come due. But the new awards are generally made in the existing fiscal year.

Senator SCHWEIKER. And when are we planning to award them again?

Mr. WOLFF. In the fourth quarter. We are apportioning it for the fourth quarter.

Senator SCHWEIKER. What I'm afraid of happening here is that from my viewpoint of serving on both the Human Resources and Appropriations Committees, it will be a miracle if we get the President's mental health bill out and fund it. Now, I happen to be very positive about his bill. Mrs. Carter testified before our committee and I think there are some very good elements of what the proposal brings about.

But it is going to be a miracle to get that program through in time for this committee to put funds in it. And the chairman, Mr. Magnuson rightly so, takes the position that without authorization, he's not going to fund it. So what I see happening is a situation where we're going to penalize the old program.

We have already not only traded off $30 million from this program, but we have another cut projected into the new year for starts as well. And if we end up without the new authorization in time to get this committee's approval, we will be in the position of not funding the new program and not putting funds in the old program. And I think this is a very real problem. There is a very real danger.

And that is exactly what this committee did on all the education and all the other programs last year when it didn't have authorizations—it deferred new appropriations. There is a very real situation that that is going to happen exactly that way this year. The community mental health people are vitally concerned about it, and they should be. And I think we may well get to the point where we wind up in the worst of both worlds.

Dr. KLERMAN. As was indicated here, we do not intend to let those funds go unexpended. Congress has indicated with its appro-

priation that those funds are available and our understanding is that they will be released for expenditure in the latter quarters of the fiscal year.

Senator SCHWEIKER. Well, I'm not sure when that point is.

Mr. WOLFF. It is in the fourth quarter. We will be allocating in the fourth quarter, either under the existing authority or the new authority, if we have it.

Senator SCHWEIKER. Well, does that mean that you will not send up a deferral on this money until the last day of the fiscal year?

Mr. WOLFF. Absolutely not.

Senator SCHWEIKER. You will not do that?

Mr. WOLFF. No.

TIMELINESS OF NEW SERVICE PROPOSAL

Senator SCHWEIKER. Well, that's a help. These funds are not in reserve. They have been apportioned for the fourth quarter. And clearly, if we are not in time to get the President's program in place—we're going to make every effort in the health committee to be in time, but it's going to take a lot of work—then this money would be spent under the old program?

Mr. WOLFF. Yes.

Dr. PARDES. I might comment, Senator, that we are continuing to receive community mental health center applications at this point.

Senator SCHWEIKER. You're proceeding on the basis that you could use this option if the other doesn't pass?

Dr. PARDES. Yes.

GRANTS TO STATES

Senator SCHMITT. Doctor, your legislative program proposed for later transmittal consolidates funding for alcohol, drug abuse, and mental health into a grants to States program. What will be the formula used to determine the amount each State will receive for these disciplines in that program?

Dr. KLERMAN. The proposal which will be sent to the Congress shortly calls for combining the State formula grants moneys for alcoholism and for drug abuse with the 314(g) moneys for mental health at 90 percent of the sum total for fiscal year 1979. That comes to about $99 million. Among the proposals that are being considered would be various internal formulas to protect the fields of alcoholism and drug abuse since it is the alcoholism moneys which make up approximately 50 percent and drug abuse about 40 percent of the total under current authorization and appropriation.

However, the bill has not yet been completed, and I cannot tell you in detail about the fiscal mechanisms to be employed by the Government.

Senator SCHMITT. I think your budget indicates it is only going to be funded at 90 percent of the level of the combined programs in fiscal year 1979. Who's going to pick up that—absorb that 10 percent?

Dr. KLERMAN. Well, our hope is that by combining programs that there will be significant savings at the State level to make up for the net dollar difference.

Senator SCHMITT. What about the administrative savings at the Federal level?

Dr. KLERMAN. I do not think that this would make any significant difference in as much as the formula grants are relatively easy to administer at the Federal level.

Senator SCHMITT. You're expecting the States then to be able to use the money more efficiently?

Dr. KLERMAN. The Governor would designate these moneys according to local-State perceived needs and would effect savings through combining programs of, say, alcohol and drug abuse in dealing with the elderly or children.

ADMINISTRATIVE OVERHEAD

Senator SCHMITT. Then are you saying that there is a 10-percent overhead at the present time in the cost of administering the program under their present guidelines?

Dr. KLERMAN. No; I think the current legislation fixes the amount of money that can be used from these formulas for administrative costs. It would not be overhead savings; it would be, hopefully, savings through program activites at the State level.

Senator SCHMITT. Well, States would probably include that at least in an indirect overhead. What I'm trying to get at is: Are the States going to have more or less bang for their buck?

Dr. KLERMAN. Well, they'll have less bucks, but hopefully more bang.

Senator SCHMITT. Are you developing any kind of justification for that?

Dr. KLERMAN. We will send a bill to the Congress within the near future.

TIMELINESS OF GRANTS TO STATES

Senator SCHMITT. Well, again, I'm not familiar with the process, but I think it is going to be difficult for this committee to be looking at this budget which assumes that program is going to be in place. At the time we don't know what the program is and how these costs are going to be divided and how the funds are going to be divided.

Dr. KLERMAN. We'll make every effort to submit the bill in the near future.

REDUCTION IN GRANTS TO STATES

Senator SCHMITT. Doctor, if we do not get a bill or if that bill is not passed, the authorizing bill, should the money go back into the old program?

Dr. KLERMAN. From the point of view of maintaining program continuity, I would hate to see any reduction in the total program in this field. Our feeling is that the consolidated State grant is a preferable way to proceed.

Senator SCHMITT. But you're not quite sure it is a reduction?

Dr. KLERMAN. Well, the proposal would be a 10-percent dollar reduction.

Senator SCHMITT. But I mean a reduction in what you can get for the money, including inflation.

Dr. KLERMAN. We would hope that the States——

Senator SCHMITT. That is really, I guess, more like a 20-percent reduction, isn't it, if inflation is taking 10 percent?

Dr. KLERMAN. Yes.

Senator SCHMITT. So that is a pretty healthy reduction for the States to make up some way by having more management flexibility, which I think they should have. Don't get me wrong, but we're going to have to have obviously more information about this program before we make a final decision on this in the budget area.

Senator Schweiker?

SHORTAGE OF MENTAL HEALTH PERSONNEL

Senator SCHWEIKER. Last year we were told that HEW was projecting a shortage of 10,800 psychiatrists by 1980 and a projected shortage of psychiatric nurses and social workers in this fiscal period.

What does your fiscal 1980 budget do to deal with these shortages?

Dr. KLERMAN. I will make a general comment, and then I think Dr. Pardes could answer that in detail. This committee and the overall House and Senate increased the appropriation for clinical training to the National Institute of Mental Health by an additional $6 million in fiscal year 1979 which has contributed greatly to augmenting the capacity of the system.

Dr. Pardes can describe in detail how those moneys are being spent and what the plans are for meeting the personnel needs in this field.

Dr. PARDES. Senator, we have undergone a redirection of our entire training program. We recognize the shortage problem in terms of numbers of U.S. medical graduates going into psychiatry. Our concern, however, is particularly around the question of settings which have difficulty recruiting people in the mental health field. And as a result, we are directing our program so as to insist that those basic mental health training programs we support address significantly the priorities identified by the commission, which include facilities and settings which have had difficulty recruiting mental health people.

In addition, we intend to request authority for a payback requirement for those people receiving support through the mental health training programs in order to insure that we get service payback from those people whom we support and that that service payback be in the areas of greatest need and greatest difficulty.

SIZE OF SHORTAGE

Senator SCHWEIKER. Do you still project the same figures? I mean, have those figures changed any from last year or not?

Dr. PARDES. I do not think we would project precisely the same figures. There was one survey which showed some 3,200 positions open right now in areas that have difficulty recruiting, in the mental health area. It was our feeling that the mental health training over the years has made a substantial impact on the total supply of people in the mental health professional field.

Our concern at the moment is more addressed to the question of special areas in mental health, such as geriatric mental health, and children's mental health. We are concerned about the number of minority providers in mental health and particularly concerned

about the question of providers getting to locations where we have difficulty recruiting.

Senator SCHWEIKER. Thank you.

[CLERK'S NOTE.—Subsequently, Dr. Pardes provided additional information on the supply of and demand for mental health professionals. It appears on p. 810.]

SHIFT OF EMPHASIS

Senator SCHMITT. I would like to follow up on that question a little bit, to make sure I understand it. You are going to have a shift, then, in the percentages of funding available for stipends, a shift in terms of emphasis in various professions, is that correct?

Dr. PARDES. Could you clarify that?

Senator SCHMITT. You're going to shift your emphasis in the granting of stipends with respect to various professions—psychologists, nurses, psychiatrists—is that correct?

Dr. PARDES. We feel that the actual stipends within residency training in psychiatry can be gotten from the service institutions with which the training institutions are affiliated. Therefore, we are attempting to eliminate those basic residency stipends, which amount to a rather modest amount of our training support, as I say, because we feel those funds are available from service institutions with which the training institutions are affiliated.

We will continue our pattern of supporting programs in all the disciplines. In other words, we feel that mental health has to be addressed by a multidisciplinary effort. We are trying to stimulate larger numbers of U.S. medical graduates, first of all, by stating publicly that there are difficulties in terms of introduction, shortages of U.S. medical graduates in psychiatry and second, by working across agencies within the Government to stimulate larger numbers of medical students in the U.S. medical schools to go into psychiatry, to take National Health Service Corps scholarships.

Senator SCHMITT. Well, do you like the balance, the rough balance that this program presumably will create, or are the imbalances going to continue?

Dr. PARDES. I think that we feel that if you want to talk in terms of the stipends——

Senator SCHMITT. No, the mix. I should have said the mix of various professions that are dealing in this area.

Dr. PARDES. I do not think that we perceive a major problem in terms of the mix of professions in the field. In other words, we feel that we are generating adequate numbers of various mental health professionals.

We are concerned because a new problem has developed specifically within the psychiatry area, and that is that the numbers of people who had come into psychiatry were substantially fed by the foreign medical graduate pool, and legislation has restricted that pool. There has not been a corresponding increase in U.S. graduates. In order to attend to that, we are trying a variety of ways to stimulate medical students' interest in psychiatry in order to address the need.

Senator SCHMITT. In this training area, the budget looks a little bit like a roller coaster, and I would just quote here. In fiscal year 1978, we had $84.4 million. Enacted for fiscal year 1979 was $90.4 million. There was a supplemental to bring that to $92.9 million, almost $93 million. And then in 1980 we are down to $89.4 million.

Is there a logical explanation for that?

Dr. PARDES. Well, the administration budget request in 1980 essentially is equivalent to the administration request for training last year plus a $2.4 million additional, specifically addressing the primary health care or general health care concern. That particular concern comes from recognition of the fact that a large number of mental health problems are seen, diagnosed, treated in the general health sector, and we would like to make a very heavy emphasis on the mental health psychological and psychiatric training of general health people.

So that the training budget for this year essentially represents a $2.4 million increase over the administration request of last year.

Senator SCHMITT. Well, we may follow up on that for the record. It is not clearly obvious.

Dr. PARDES. Are you saying, what accounts for the dollars going up and down?

Senator SCHMITT. Yes.

Dr. PARDES. The Congress had put in a $6 million increase in last year's budget above the President's budget. That took the budget up $6 million.

Senator SCHMITT. But then the President is asking for another $2.5 million on top of that in the supplemental, right?

Dr. PARDES. No, the President is essentially asking for $2.4 million over the budget suggested by the President in the previous fiscal year.

Maybe Mr. Augustson could address that directly.

Mr. AUGUSTSON. In 1979 we have $2.5 million in a supplemental. That is to bring us back to our original request in terms of research training. The continuing resolution reduced research training by $2.5 million.

Senator SCHMITT. So you're trying to get up to what you asked?

Mr. AUGUSTSON. Yes, in terms of the supplemental.

Senator SCHMITT. But then you're dropping down again this year.

Mr. AUGUSTSON. Well, we're dropping down in relation of the $6 million that the Congress added in 1979.

Senator SCHMITT. What was your budget request in fiscal year 1979?

Mr. AUGUSTSON. Our budget request $86.9 million.

Senator SCHMITT. $86.9 million, and we enacted $90.4 million.

Mr. AUGUSTSON. You enacted $86.9 million, plus $6 million, minus the $2.5 million for research training.

Senator SCHMITT. We enacted $90.4 million and you're asking for another $2.5 million.

Mr. AUGUSTSON. Right, for research training.

Dr. PARDES. We are dealing with two different components of training. In the research training area, as I understand it, within the last congressional year there was an opportunity to consider

the research training component of the presidential suggestion. I was talking before about clinical training.

Dr. KLERMAN. If you take the appropriation for fiscal year 1979 with the $6 million added into the request, plus the supplemental, the request for 1980 is slightly below the appropriation for fiscal year 1979.

Senator SCHMITT. And I don't understand what you are going to cut back. Was that $6 million that Congress added specific?

Dr. KLERMAN. The language of the congressional appropriation directed that the moneys be spent by NIMH for professional and specialty training in the target areas of children and youth.

Senator SCHMITT. In fiscal year 1980, you're saying you don't need that much, so you're going to cut back there, is that right?

Dr. KLERMAN. Well, in a tight budget year, it was necessary to make some priority decisions.

Senator SCHMITT. I understand. You don't have to justify it. Just explain it.

That is where the cut is, is that correct?

Dr. KLERMAN. Yes.

Senator SCHMITT. But I guess the problem is that you didn't agree with what the Congress has done. They did not give you enough in one area, they gave you too much in another; is that correct?

Dr. KLERMAN. We were very pleased to see the Congress interested in this area. However, by the time the fiscal year 1980 budget process came around, we were faced with the necessity to reconcile our priorities.

Senator SCHMITT. Doctor, I think it's clear now why that is moving around like that, and we will see what we can do with it.

RELATIVE SIZE OF INSTITUTE REQUESTS

In your 1980 budget request, including those resources in your request proposed for a later transmittal, we have a large increase for mental health, while requesting decreases for drug abuse and alcohol abuse activities. Don't you think you've gone a little bit overboard in support of the recommendations of the President's Commission on Mental Health, while ignoring substantial problems which exist in the areas of alcohol and drug abuse?

Dr. KLERMAN. Well, I do not think that when the two additional appropriation items come in, the $99 million for the consolidated State formula grants plus the $99 million for the community mental health programs, there will be the decrease that now may appear. It is true that the largest amount requested will be about $60 million for the Mental Health Institute. At the same time, we will be requesting some $16 million in addition for alcoholism, and proportionately that represents a significant increase.

In the case of drug abuse, we are requesting additional moneys, as recommended by the President's Commission, for research in the area of over $7 million.

Of course, in all three areas there are significant increases, although it is correct that at this time the major increases are in the mental health field.

Senator SCHMITT. Well, there is a major increase in the individual programs, but the net result is a decrease in alcohol and drug abuse requests, right?

And you're saying, because there is synergism, that is made up by the increases you have asked for elsewhere?

Dr. KLERMAN. The figures that we have at this moment do not reflect the $99 million for the proposed formula grants which would be forthcoming, and at that point the sum total for the agency will be greater than the current appropriation.

Senator SCHMITT. Oh, I see. You just haven't made all of the requests you're going to make?

Dr. KLERMAN. There will be two other requests coming forward, $99 million for the supplemental programs in the combined State formula grants, plus $99 million additional for the projected community mental health program.

Senator SCHMITT. Senator Schweiker says that is a very iffy proposition under the operating rules of this committee. So it may well be that we're going to see a major decrease this year in drug abuse and alcohol-related activities.

Dr. KLERMAN. That is not our intent.

Senator SCHMITT. It may not be your intent, but it may be what happens legislatively.

COORDINATION WITH OTHER AGENCIES

As an aside here, Doctor, do you work closely in coordination with the law enforcement and other activities related to alcohol and drugs?

Dr. KLERMAN. Oh, yes, both the alcoholism program and the drug abuse program have very significant and successful activities with LEAA and the Department of Transportation.

I think Mr. Archer and Mr. Besteman can describe those.

Mr. BESTEMAN. In drug abuse under the auspices of the Domestic Council, the Institute participates with the Customs Service, Drug Enforcement Administration, the State Department and the Coast Guard in a biweekly meeting. These meetings focus on the activities of our agencies with particular concern for the concerted impact on the drug abuse problem of the total Federal effort. This relationship has gone on for the last 2 years.

INTERDICTION OF DRUG TRAFFIC

Senator SCHMITT. Are you satisfied with the level of interdiction that is occurring with respect to drug traffic into this country?

Mr. BESTEMAN. I don't like to use the word "satisfied." I am encouraged by the fact that interdiction is rising rapidly for cocaine and marihuana. Also, it seems to have caused the purity of heroin to be at the lowest that I can recall in my career. Further the retail price of heroin is extremely high at the present time.

Senator SCHMITT. Profit is up and the supply is down?

Mr. BESTEMAN. Well, profit may be up, but let's say that the addiction and the number of people that are being damaged, the number of overdose deaths that are being reported in terms of any given period, hospital emergency room events, et cetera, are all down very significantly. We feel very good about that.

Senator SCHMITT. It's my understanding that across the Southwestern border, that the Customs Service people estimate that they actually interdict only about 4 to 5 percent of the total traffic. So apparently there is an awful lot still coming in, even though it may be of lower quality.

What percentage decrease in the evidence of hard drug activity do you see from your clinical side?

Mr. BESTEMAN. One of the most dramatic things that has happened in our treatment system, which we monitor on a monthly basis, is that there has been almost a 10-percent decrease in the last calendar year in the number of people presenting themselves for treatment for heroin addiction.

This is the largest single drop in a 1-year period that we have had in the history of our statistics.

Senator SCHMITT. Do you think you can attribute this to any one factor?

Mr. BESTEMAN. I think you can attribute it to a combination of factors. The fact that we are no longer getting illicit supplies of heroin via Turkey. The fact that the Mexican Government has been very aggressive and cooperative about reducing the production in their country.

The fact based on reasonable data, that shows that the general pool of addicts is being reduced through some success in treatment. I think they all work together.

Senator SCHMITT. So at the very least, though, the interdiction, the reduction in the supply is of a direct assist to your activities, is that correct?

Mr. BESTEMAN. If we did not have an aggressive interdiction program in heroin, I do not know of any way in which we would be able to survive in the treatment and prevention area.

Senator SCHMITT. In another forum, I am trying to assist the Customs and others to help you even further, and that is excellent testimony. We may ask you to come back with some more detail on that.

Mr. BESTEMAN. I would be delighted to.

DEINSTITUTIONALIZATION OF PATIENTS

Senator SCHMITT. There is a battle brewing in the scientific community, which is not unusual—that is my comment, not the question—that mental patients are being deinstitutionalized too quickly, that is, just thrown onto the streets and into mental health centers to get them out of costly State institutions.

What are you proposing with respect to services for and care of the long-term chronic and chronically and seriously mentally ill, Doctor?

Dr. KLERMAN. Let me make a general comment, and then Dr. Pardes can describe in detail the programs in NIMH.

It has been our policy to encourage the States to shift the locus of care out of the institutions and into the community, and we do this through various funding mechanisms.

However, the statutory responsibility for the direct care of these patients does rest at the State. The Federal Government does not

operate any institutions, St. Elizabeths being a notable and important exception.

The rate of progress has varied from State to State, not only the rate at which the States have deinstitutionalized, but more importantly, the rate at which they create community-based facilities to accept these patients and to provide them with various medical, mental health and residential needs.

Dr. Pardes can tell you in more detail about some of the activities now and under the new proposed act to augment the States' ability to meet the needs of patients who are being deinstitutionalized.

Dr. PARDES. The problem with chronic patients, institutionalized patients, is one of the major priorities of the Institute. I think the concern about excessively rapid deinstitutionalization has at times been appropriate. I think that the many benefits of bringing people out of the hospital and treating them in other localities, has been well-documented.

But there have been areas where I think that movement has gone swifter than it should and without adequate preparation of the community.

Now, our concern is that we be attentive to the services wherever mental health patients are treated. In the new systems act, given the comments Dr. Klerman made, we are proposing a new set of interactions and cooperations between us and the States. This, referred to as cooperative agreements, would allow us to discuss with the State its situation regarding the appropriate treatment and rendering of services to chronic mental health patients, to identify, over the course of the year likely developments within that given State, and to then give States funding support in order to help accomplish some of these objectives.

One of the particularly attractive features of that program is the notion of individual negotiations between the Federal Government and States, which would allow us to take a State from where it is in terms of moving forward on its programs for the deinstitutionalized patients.

MENTAL RETARDATION

Senator SCHMITT. Next I would like to cover some aspects of mental retardation, which is one area in many respects where we may have the opportunity to prevent mental health problems before they occur, a true prevention.

In October 1977 the General Accounting Office issued a report criticizing HEW for a lack of programs to prevent and/or reduce the incidence of mental retardation. What has ADAMHA done to respond to these GAO criticisms?

Dr. KLERMAN. Well, up until, I think, 1968, the responsibility for research in mental retardation did lie with NIMH. However, with the creation of the National Institute on Child Health and Human Development, the research responsibility in the field of MR for the most part is now in that agency.

We are responsible for assisting them in areas of psychosocial and psychiatric aspects. But the primary responsibility for research on the biochemistry and in fields like genetic counseling lies with the National Institute of Child Health and Human Development.

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We have an excellent cooperative arrangement with them, but the authorization and the funding for those programs specifically are with that agency.

The service programs for the mentally retarded are through the maternal and child health programs of HSA, the Health Services Administration, and through the Office of Human Development Services.

Again, we cooperate very closely with them; and the most important advances in prenatal care that you identify are, however, not our direct responsibility.

SIGNIFICANT ALCOHOL RESEARCH BREAKTHROUGHS

Senator SCHMITT. Not even with respect to drugs and alcohol?

Dr. KLERMAN. Now, when it comes to alcohol, there has been a very significant breakthrough in the determination of the fetal alcohol syndrome. There we have a very notable achievement in the delineation of that syndrome, coming from research developed and supported by NIAAA. We are now developing a special program on that, again, in cooperation with other parts of the Public Health Service and also the Department of the Treasury.

Mr. Archer can tell us more about that.

Mr. ARCHER. When you talk about significant breakthroughs, this is one area we would like to emphasize, because this is one of the areas of mental retardation which is truly preventable.

We have looked at the estimates, the incidents, and problems of mental retardation and we have found that alcohol related, fetal alcohol syndrome is the third leading cause of birth defects with associated mental retardation. So we feel this is a very significant area which we have emphasized in our research and are continuing to emphasize.

We are working very closely with FDA and the Bureau of Alcohol, Tobacco, and Firearms in the development of programs and material to educate health care practitioners as to the dangers of the use of alcohol during pregnancy. We do feel this is an area where there can be a significant cost-benefit by the reduction of mental retardation. And there is also some evidence—it appears that this could also have some impact on other types of behavioral problems, such as hyperactivity.

INFORMATION DISSEMINATION

Senator SCHMITT. Are you carrying out any kind of a program to see how successful these information dissemination activities are?

Mr. ARCHER. Yes, as a part of the 1980 Department's alcohol initiative we are planning to evaluate the effect of these programs to find out, first of all, whether dissemination of fetal alcohol syndrome material has changed the attitudes toward the actual use of alcohol at the time of pregnancy. And we're gathering the baseline data right now, in cooperation with the National Center for Health Statistics on the present rates of fetal alcohol problems.

Senator SCHMITT. Now, you started your efforts primarily—I guess exclusively—because of your alcohol-related responsibilities?

Mr. ARCHER. Plus, alochol is the drug that is most widely used.

COORDINATION OF EFFORT

Senator SCHMITT. But do you all have the authority necessary to expand this experience now into the fields of tobacco or soft drugs and hard drug activities, marihuana, and so forth?

Mr. ARCHER. We do not have that authority ourselves. We have looked at the question.

Senator SCHMITT. Don't you have the base now of experience that should be used?

Mr. BESTEMAN. The National Institute on Drug Abuse has all the substances controlled under the Controlled Substances Act, which includes marihuana and other psychoactive materials. We also have been given the responsibility, from the Secretary, to do a certain amount of basic research on smoking. This responsibility is in the Secretary's smoking initiative.

Senator SCHMITT. Do you all work together on this? Are you using the same people?

Mr. BESTEMAN. Sometimes. We have some investigators that are dealing with both alcohol and other drugs at the same time and using the same methodology.

Senator SCHMITT. Well, that is my concern. You do feel that you have a good working relationship, so there is not duplication of effort, but there is also the synergism that such an effort would entail?

Mr. ARCHER. Senator, we are. We cannot research these areas without considering all the drugs and substances—more importantly, in the area of intervention and treatment.

ALCOHOL AND TOBACCO

Senator SCHMITT. How do you separate alcohol from somebody who is also a very heavy smoker? I presume you have had to look into that?

Mr. ARCHER. You can't. But what tends to happen is a person who is a heavy alcohol drinker will more likely be a heavy tobacco user or a heavy user of other kinds of substances as well. As we look at the methods of prevention, and the messages—we have to provide messages that not only impact on alcohol, but also on all the other drugs that would be utilized, as well as tobacco.

Senator SCHMITT. Now, do you have in place an information dissemination project or program that is fixed enough that you know what you're doing, and you can evaluate its results?

Mr. ARCHER. We have some examples. What we are planning in the 1980 alcohol initiative in this budget is to expand and provide a nationwide network of public information and educational programs, particularly for women of childbearing years. That is a major part of this initiative—it is not in place at this particular point in time, but we have laid the groundwork.

ALCOHOL INITIATIVE AND THE BUDGET

Senator SCHMITT. Where is that hidden within these numbers?

Dr. KLERMAN. It is part of the community programs line for NIAAA. It includes demonstration projects and prevention with regard to the fetal alcohol syndrome.

It is important to note that the recent decision of the Department of Treasury puts a burden on the industry to cooperate with Government in developing some educational programs, and the decision of the Treasury also required baseline evaluation prior to such educational efforts, as well as ongoing assessments, along the lines you indicate, to determine the extent to which new efforts affect incremental change.

The FDA has proposed the possibility of labeling alcoholic beverages as injurious to the health of pregnant women. The Department of the Treasury, which has the legal authority for this, felt that an educational program, directed both at health care providers and at women of childbearing age should be attempted before any regulatory efforts through labeling were put into place. We are looking forward to cooperating with the industry, the medical profession, and with the Treasury, to develop a comprehensive program.

Senator SCHMITT. Well, is it in the research budget?

Dr. KLERMAN. It's spread throughout the research budget and also the prevention and training budget.

Mr. ARCHER. A proportion of the research budget is to increase our research capabilities.

Senator SCHMITT. In terms of information dissemination and public education, is there a centralized——

Mr. ARCHER. That is located within a part of our community program budget line.

Senator SCHMITT. Is there someone who is overseeing that?

Mr. ARCHER. Yes, our Prevention Division.

Senator SCHMITT. Well, we will have a few more questions on this subject for the record relative to the President's——

Dr. KLERMAN. There is increased money in the budget for both research and prevention activities in alcoholism, and some of these are identified for fetal alcoholism.

Mr. ARCHER. Senator, we have identified within the alcohol initiative, $1,450,000 aimed at developing intervention techniques to disseminate information on the effect of alcohol on the fetus.

RESEARCH ON SMOKING

Senator SCHMITT. Do you have all the authority you need to look at tobacco?

Mr. BESTEMAN. Neither of us—neither the Drug Institute nor the Alcohol Institute—has any legislative authority to work on tobacco. The Secretary has designated the roles the various health agencies will take. Because of the striking similarity in the consumption of tobacco and an addictive substance, we have been asked at the Institute on Drug Abuse to investigate the addictive-habituation characteristics of tobacco, particularly nicotine. We are concerned with research on the addictive behavior associated with tobacco.

We are not charged with any of the prevention nor any of the treatment or cessation aspects. We are looking at tobacco use in connection with our drug abuse prevention, because, as Mr. Archer has pointed out, you cannot isolate the consumption of one substance from another when you take on a prevention campaign.

Mr. ARCHER. Senator, we have done one very important thing though, and that is that even if you control smoking, the use of alcohol by itself has a different kind of effect on the fetus than does smoking, so the effect is far more significant as far as long-term damage.

Senator SCHMITT. As far as you know.

Mr. ARCHER. As far as the research has shown.

Senator SCHMITT. Research has a strange way of surprising us though.

Mr. ARCHER. Yes, it was only recently that people began to agree that alcohol had an effect on the fetus.

USE OF 1979 RESEARCH FUNDS IN MENTAL HEALTH

Senator SCHMITT. Speaking of research, in last year's report, the committee acknowledged the need for an increase in mental health research; with the $21,787,000 increase over the 1978 budget it was hoped that we might get a better grasp on one of the most misunderstood of all human afflictions in both cost and human suffering. What specific programs have been established to further our knowledge of mental health?

Dr. KLERMAN. Do you mean in terms of research funding?

Senator SCHMITT. Yes, in this increase.

Dr. PARDES. We have initiated a number of new efforts within mental health research. I would emphasize again some of the problems of the period of time during which mental health research support has not grown as actively as other areas of health research that the Federal Government has supported, but we have introduced additional efforts in the area of treatment assessment research.

We are also increasing additional efforts in the area of clinical research, research related to the basic understanding of mental disorders, as well as attempting to get increased research started in the therapeutics of the major mental disorders.

We are also concerned about research related to issues like the classification of mental disorders and the knowledge of mental disorders. And we're also concerned about research relating to particular focused populations such as the elderly, children, et cetera.

We have a broad array of research thrust.

One of the other ones that we are now focusing on particularly is the question of additional prevention research, which I was going to mention earlier in relation to your question about trying to get research ongoing which has long-term benefits as opposed to immediate impacts.

RELATION TO 1980 BUDGET INCREASES

Senator SCHMITT. Now, the areas you've just described would be the ones that have been increased and emphasized in the fiscal year 1980 budget?

Dr. PARDES. Well, what we feel is that we need some continued enrichment of a variety of areas in mental health research, but with a major emphasis on prevention and other priorities identified by the President's Commission. I emphasize again that the status

of the mental health research community in, let's say, the early 1970's had been one of some difficulty in terms of adequacy of support. I would characterize the situation in the mental health research area amongst that group of people who would be prospective investigators, as well as existing investigators, as one of some distress in terms of the adequacy of mental health research support.

So we would see ourselves as——

MENTAL HEALTH RESEARCH PROGRAMS

Senator SCHMITT. Well, will you supply us with a specific summary of those mental health research programs that are being increased in terms of budgetary emphasis in the fiscal year 1980 budget—and, also, with that, again some of the new findings that have resulted from your most recent mental health research efforts?

Dr. PARDES. Yes. We'll be glad to.

[The information follows:]

NIMH RESEARCH PROGRAMS
FY 1980 Budget Increases and Recent Research Findings

I. FY 1980 Budget Increases

The 1980 research budget request totals $160,168,000, representing an increase of $27,381,000 over the 1979 level. All of the proposals are consistent with recommendations of the President's Commission on Mental Health (PCMH). Research increases are distributed among the following major problem areas:

Area of Study	Thousands of Dollars 1979	1980	Change
1. Prevention	---	$ 6,000	+6,000
2. Major Mental Illnesses:			
a. Schizophrenia	$14,718	17,685	+2,967
b. Depression	12,850	15,490	+2,640
c. Basic neurological and behavioral science studies	43,297	49,692	+6,395
d. Neuroses & personality disorders	4,455	5,164	+709
e. Child & adolescent psychopathology	6,774	8,179	+1,405
f. Neurological disorders	10,565	12,293	+1,728
3. Incidence of Mental Illness	3,945	5,391	+1,446
4. Health Services Delivery	8,802	10,263	+1,461
5. Other programs A/	27,381	30,011	+2,630
Total	132,787	106,168	+27,381

A/ Includes programs on aging, treatment assessment research, and social problems. The 1979 and 1980 levels also reflect the result of some overlap among areas of study, as some activities may address two or more target areas.

Cutting across all of the research categories just listed is an additional PCMH priority, which is to restore and maintain the total research capacity, at a level which will keep up with inflationary trends.

II. Examples of Recent Research Findings

Breakthroughs having quantifiable impact on the general population are usually the result of groups of interrelated research projects, with each project addressing a small segment of a larger problem. However, the following individual summaries represent examples of studies which have appreciable significance in their own right.

Electroconvulsive Therapy

Electroconvulsive therapy (ECT), widely used for several decades as a treatment for depression, has been a subject of increasing controversy in recent years. Many professionals and members of the public have expressed concerns over both the effectiveness and safety of ECT as a form of treatment.

An NIMH-sponsored report on the efficacy and impact of ECT (now in the process of being published) indicates that ECT is, in fact, an effective treatment for severe depression. Although the treatment does produce some side effects, the risk level associated with its use has been found acceptable - particularly in view of the seriousness of the disease. The more severe the depression, the more effective and desirable ECT becomes as a form of treatment. Although more research is needed, this initial finding is considered significant, since ECT represents a reasonable level of risk as a treatment for one of the most disabling of mental illnesses.

Schizophrenia

Almost half of the nation's hospitalized psychiatric patients suffer from schizophrenia. Approximately one third of the patients released require re-hospitalization within one year. Because of the magnitude of this particular mental health problem, NIMH is spending over $14 million this year for research on schizophrenia. As the result of past efforts, several findings have emerged, and these are proving valuable in charting the course of future research.

Contrary to earlier beliefs, NIMH supported studies indicate that the severity of the symptoms in the early stages of schizophrenia may not be as good an index of seriousness as early onset and poor functioning prior to onset. This finding is significant as a predictor for the length and chronicity of the disease in specific individuals. Another study has indicated that the use of day care after hospitalization significantly reduces the chances and length of re-hospitalization. This finding is important, when dealing with a disease characterized by the lifelong prospect of recurring inpatient hospitalization. Most of the completed studies point toward the importance of emphasizing continuity of care, including outpatient treatment, day care, and community placement.

Childhood Depression

The area of childhood depression has been characterized by an absence of systematic approaches to the origin, classification, diagnosis and treatment of this disorder. The problem has been complicated by several factors, including (1) the traditional benchmarks of disorders and pathology which apply to adults do not apply to children; (2) there are strong ethical issues relating to the use of drugs in therapy for children; and (3) there have been few controlled studies from which information could be derived.

New NIMH-funded studies now underway show promise for addressing many of these problem areas, including (1) the provision of basic normative data on sub-types of childhood depression; (2) the development of improved diagnostic instruments and techniques; (3) the clarification of previously vague clinical descriptions of depressive symptoms; and (4) the development of a better understanding of the role and effectiveness of drug therapy for children.

RESEARCH ON AGING

Senator SCHMITT. Is there one you would like to discuss?

Dr. KLERMAN. Let me give you an example of one where new funds have allowed us to dramatically increase our capability. In part because of congressional directives, in the field of aging in 1978 there was $4 million spent. With the new moneys in fiscal year 1979, the research on aging increased to $6.2 million.

In fiscal year 1980, with the funds we are asking for, we will increase research on aging, to $7.5 million. New advances in neuropathology and neurochemistry and psychology, enable us to feel that the field of mental health and aging is one that can provide payoff in terms of the problems you identified earlier.

USEFUL ACTIVITIES FOR LONG-LIVED CITIZENS

Senator SCHMITT. Now, one of a couple of followup questions here: One of the problems is that we, through our unbelievable increase in medical technology and understanding of how to make life longer and more comfortable for people, we have an increasingly large group of long-lived citizens, but we are making very little progress in giving them useful activities or making available—I shouldn't say giving, but making available useful activities for these people. Isn't that one of the fundamental health problems that these people face is: Just what do I do now that I've retired?

Dr. KLERMAN. Well, I think you're right. One of the things that I think we are proud of is a very successful cooperative relationship between our programs and that of the National Institute on Aging. There is a Joint Responsive Conference on the problems of women as they age. There is also a special recent conference on recreation and social aspects of aging.

Senator SCHMITT. What about the resource that they represent? My God, the experience of people who have retired—and we just say, "Forget it; we don't need it anymore, the rest of us, those that are 30, 40, 50 years old. We'll get along without that experience."

Dr. PARDES. I think that has been a profoundly disturbing issue.

I was personally very pleased to see the question of arbitrary retirement had been set aside, that was a most useful development, so that older people who can make major contributions—perhaps even better than some of us so-called younger ones—can still make contributions to society.

I think there is another issue, which is the question of the entire society attitude about elderly people and recognizing their utility. We have tried to have educational efforts and focus on getting rid of the number of myths around being older.

Many people have all kinds of notions about older people not being able to function and not being able to work and not being able to live regular lives, which include working, loving, et cetera. And we have tried to be educational.

RELATION OF BUDGET TO AGING PROGRAMS

Senator SCHMITT. Can you be very specific for the record on how your budget this year relates to the philosophy—if it is, in fact, your philosophy—that our long-lived citizens are a resource for our society, rather than a burden, or someone that we have to provide mental health care for?

Dr. PARDES. I can give you a concrete example on that. The NIMH has instituted a scholars program whereby we can take a person who is—I forget your term for it, Senator——

Senator SCHMITT. Long-lived—that is not mine; the Soviets used that.

Dr. PARDES [continuing]. A long-lived person to come and function as a scholar, and we've instituted that program this year; and we have a distinguished scholar in geriatric mental health who is one of our long-lived citizens.

CENTER FOR STUDIES OF MENTAL HEALTH OF THE AGING

Senator SCHMITT. What is the status of the Center for Studies of Mental Health and Aging?

Dr. PARDES. That center has become operational.

Senator SCHMITT. Does it have a charter?

Dr. PARDES. Yes, it does. In 1975, the Administrator authorized its establishments as an organizational entity. In July 1978, the then-acting Director of NIMH chartered it to actually support grant programs.

Senator SCHMITT. Can we have a copy of that for our record?

Dr. PARDES. Sure.

[The charter follows:]

The Center for Studies of the Mental Health of the Aging was first established (chartered) as a component of the NIMH Division of Special Mental Health Programs on August 4, 1975. Authority to establish components within NIMH Divisions was vested, at that time, with the Office of the Administrator, Alcohol, Drug Abuse, and Mental Health Administration. This authority was subsequently delegated to the NIMH and on July 13, 1978 the Acting Director, NIMH revised the Center's charter to authorize it to establish its own separate program budget and thereby provide financial support for mental health projects relating to aging. The functional statement (i.e., charter) for the Center follows:

CENTER FOR STUDIES OF THE MENTAL HEALTH OF THE AGING, DSHP

(1) Serves as focal point for and coordinates Institute activities in mental health of the aging; (2) analyzes and evaluates current research and related program developments in this area; (3) stimulates, develops, and supports programs of research in the mental health of the aging including (a) the etiology, diagnosis, course, and prevention of mental disorders in later life; (b) program development, social problems, and social policy research in mental health and aging; and (c) research in treatment and the delivery of mental health services to the elderly; (4) stimulates, develops, and supports clinical services and research training programs pertaining to the mental health of the aging; (5) collaborates with other organizations within the Department of Health, Education, and Welfare, such as the Administration on Aging and the National Institute on Aging, as well as the Division of Mental health Service Programs, NIMH to facilitate program development; (6) collaborates with other organizations such as Federal, State, and local agencies, community mental health centers, voluntary organizations, and planning boards to facilitate program development; (7) develops, communicates, and disseminates information on the utilization of significant research results; (8) stimulates communication of appropriate information through consultation, technical assistance, conferences, and publications.

FUNDS FOR AGING PROGRAMS

Senator SCHMITT. How much money are you allocating for it?

Dr. PARDES. We have $4.7 million in total for extramural research on aging.

Senator SCHMITT. Is that 1979?

NATIONAL INSTITUTE OF MENTAL HEALTH DISTRIBUTION OF FUNDS FOR AGING PROGRAMS

Dr. PARDES. Yes; we also have $5.7 million in 1980. In addition, we have training programs also, which the Center for Aging is promulgating.

Senator SCHMITT. Now, is that going to go through the center—that whole $4.7 million?

Mr. GOODY. A portion of it.

Senator SCHMITT. Could you provide us a breakdown of how that will be distributed?

Mr. GOODY. Certainly.

[The information follows:]

The fiscal year 1979 NIMH extramural research budget for programs relating to mental health problems of the aged totals $4.7 million. At the present time, these funds are distributed among the following NIMH programs:

Program:	*Amount*
Clinical research	$320,000
Applied research	206,000
Psychopharmacology	254,000
Small grants	40,000
Research scientist	81,000
Epidemiology	244,000
Services research	1,236,000
Special mental health programs (minority, metropolitan problems, crime and delinquency)	2,309,000
Total	4,690,000

On July 13, 1978 the Center for Studies of the Mental Health of the Aging was authorized to establish its own separate program budget and thereby directly provide grant and contract support for research projects relating to mental health of the elderly. The Institute is now in the process of developing a budget for the Center. Because there are approximately 150 ongoing projects distributed among four NIMH Divisions and ten subsidiary programs, each project must be reviewed and individual decisions made concerning the appropriateness of its transfer to the Aging Center.

The process of project review will be completed and a budget assigned to the Aging Center within 60 days.

ALCOHOL AND AGING

Mr. ARCHER. Normally, aging is considered a mental health problem. I think older people have been extremely helpful to us in the alcoholism field in that we take a great deal of pride in the fact that in our budget we have emphasized development and training and recruiting of volunteers, and we have over 30 statewide programs using older trained volunteers.

POTENTIAL CONTRIBUTIONS BY LONG-LIVED CITIZENS

Senator SCHMITT. Let me give you another example, and that is that in some of the civil defense activities there is absolutely no reason why our long-lived citizens cannot be a major part, if not the core, or our civil defense activities in terms of communications and even transportation and other activities.

Obviously, there would be some physical limitations on some. But, nevertheless, it is that kind of a resource, of experience.

Mr. ARCHER. Not only that, but our research has shown us that these individuals are as effective at providing output as are more highly trained professionals.

ALCOHOLISM AMONG VETERANS

Senator SCHMITT. I think today Max Cleland, head of the Veterans Administration, stated that the major problem among disabled veterans is alcoholism. In fact, if I'm correct, he stated that 30 percent of all their problems can be attributed to alcohol.

Do you agree with that? And can you give us some specific examples of what the Institute is doing for veterans?

Dr. KLERMAN. I would agree with that.

Again, I think Mr. Archer is in the best position to explain the Institute's program in alcoholism and its relation with the VA.

Mr. ARCHER. Yes, I certainly would agree with the figure. We have had a longstanding, closeworking relationship with the Veterans Administration at the State and community levels; and in our State and community plans, our programs have been working with and used the VA as a treatment facility.

But, in addition to that, we have been pioneering in the development of homelike residential care and halfway houses, and have been encouraging referrals from the Veterans Administration in these facilities.

We have shown that these are excellent facilities and can eliminate the need for hospitalization in many cases.

So we have had, as I said, a longstanding, excellent relationship with the VA and have jointly been working on evaluation techniques and working with them in the area of training, because our problems are very similar. Plus within our treatment programs—a high proportion of individuals being treated are veterans.

ALCOHOL TREATMENT EFFECTIVENESS

Senator SCHMITT. Do you have any means by which you, again, can quantitatively or qualitatively gage the effectiveness of the programs that you have?

Mr. ARCHER. Yes; we do. Because the alcoholism programs have always been under criticism, we have been tenacious in the area of followup studies. We have been getting information on the characteristics and the extent of the problems of individuals from the time of entrance into treatment until 4 years after.

And we found that these programs are highly effective. And while not everyone does recover, those who do recover are quite productive, particularly if we can move them into a cooperative, long-term social support system such as AA. So we try to use those facilities and networks that are already in the community to fill the vacuum.

For instance, there are a number of types of individuals who have been underserved, minority groups in particular, so our programs have particularly attempted to improve the quality of treatment services to native Americans, blacks and Hispanics. The people being served in our programs are very heavily weighted toward the minorities and low-income population.

Our hope is that we can demonstrate programs that are effective and we will, as a result of this, achieve changes in the condition of the health service systems.

CHANGE IN AUTO ACCIDENT RATES

Senator SCHMITT. Have you seen any change in the accident rates, automobile accident rates due to alcohol abuse?

Mr. ARCHER. We have seen a change. I would like to say it is from a reduction of the use of alcohol, but we can't determine what the effect of the 55-mile-an-hour speed limit has had.

We think there have been a number of impacts because people are being arrested more for drunk driving. It is one of the best ways that we have found for intervention and introducing people to treatment programs, whether it's occupational or highways. Many times the pressures are such that you finally recognize and have to stop denying the problem and seek treatment.

TEENAGE ALCOHOL ABUSE

Senator SCHMITT. In this regard, what is the latest assessment of the problem of teenage alcoholism?

Mr. ARCHER. I would caution against the use of the words "teenage alcoholism."

Senator SCHMITT. OK. Short-lived citizens. [Laughter.]

Mr. ARCHER. No, I would prefer not to use the word "alcoholism" because I think we're not talking about alcoholism as such in this case.

Senator SCHMITT. Alcohol abuse, then.

Mr. ARCHER. The predominant problem is alcohol abuse. Unfortunately, most teenagers who have the problem don't live long enough to become alcoholics, because the leading cause of death in teenagers between 16 and 24 is alcohol related traffic fatalities.

Now, these are individuals who very likely would continue in their pattern and become alcoholics. So that the problem appears to us to be increasing. As we have looked at household samples, we have found that the rate at which individuals are reporting having problems, whether it be problems in the school or other types of authority figures—used to be about 10 percent. It has now increased over a 5-year period, to about 19 percent.

So there is a significant increase, and unfortunately—and one of the things we speak to in our initiatives—is the fact that these people are also underserved. Most of the treatment programs have been oriented toward older individuals and have not really spoken to the needs of the youth.

Senator SCHMITT. It's my understanding we have been steadily increasing the funding for programs related to this area. Are we not working on the right solutions, or do we not know what the solution is?

Mr. ARCHER. Senator, I think we know.

Senator SCHMITT. What is the best way to combat the problem?

Mr. ARCHER. We know some programs which seem to work well, particularly among youths in a peer counseling relationship. But even though the funds have been increased substantially, the problem has been increasing more rapidly than the funds have.

LEGAL DRINKING AGE

Dr. KLERMAN. I think that, in addition to the funds for services and prevention, I personally am impressed with the information that Mr. Archer has brought to my attention about the impact of the States lowering the legal age for alcohol use. A number of States, Michigan and Massachusetts, a number of years ago reduced the legal age of drinking, and that was followed very rapidly, I think in a cause-and-effect way, with an increase in automobile fatalities and in accidents by young people, and also by increasing vandalism in certain schools.

Senator SCHMITT. Is there a statistical analysis of this?

Dr. KLERMAN. Yes, a number of excellent studies have been undertaken to document this. And one of the things that I think should be considered in an overall prevention program is that those States which have done so should be encouraged to reconsider it. I know that is under consideration in Maryland and Massachusetts. We would encourage States to not lower the age of drinking. And also, those which have, to reconsider and raise the legal age. That would have a major preventive aspect.

Senator SCHMITT. Simultaneously with helmet laws.

Dr. KLERMAN. And enforcement of the 55-mile-an-hour speed limit.

RURAL MENTAL HEALTH

Senator SCHMITT. In the area of the extension of services to rural areas, which mental health professions will be emphasized in that effort?

Dr. PARDES. We would be emphasizing the use of all mental health professionals. That is one of the reasons that we are targeting the training programs and suggesting or requiring that those training programs address priorities including the problems of recruitment into the rural areas and people making their payback, either for the National Health Service Corps scholarships or for our supporting stipends, would have to make a payback within an array of areas including many of those that accrue to rural areas.

Senator SCHMITT. Do you have any problem in terms of the differences between the various mental health professions, as they have in other medical areas? For example, we found in New Mexico that recruiting medical professionals outside of the mental health area for rural work has gone on quite well except for internists. They just have a very special set of either real or perceived needs with respect to large urban areas, and it is tough.

We are making some progress because of a heck of a lot of diligent effort among people out there, but do you see any distinction between psychiatrists, psychologists, social workers, nurses? Does that affect your balance, or just the perceptions within the professions themselves?

Dr. PARDES. I think there is some difficulty in getting physicians to rural areas generally, and not only getting them there but keeping them there. I'm not sure that the problem is dramatically different from profession to profession. I think there are many factors which apply across the board of all the health professions.

As I say, we intend, with our training direction to try to address that across the mental health field. But I think the problem is probably applicable to most, with some minor variations.

INDIAN ALCOHOLISM PROGRAMS

Senator SCHMITT. Last year the committee directed that NIAAA initiate new Indian alcoholism projects, as the mature projects are transferred to the Indian Health Service, to maintain the 1977 level of support for Indian alcohol programs.

How many so-called mature projects have been transferred to the Indian Health Service since 1977?

Mr. ARCHER. Well, Senator, since 1977 we have transferred 88. By the end of 1980, we will have transferred 120.

Senator SCHMITT. Out of what number?

Mr. ARCHER. This would be out of a total of 153.

Senator SCHMITT. So you are moving the projects to maturity fairly rapidly.

Mr. ARCHER. That is correct. This is part of the long-term policy. However, NIAAA has funded new projects in 1977 and 1978.

I think what you have to look at is the fact of what has happened in the total. At the time when we started out, there were no Indian alcoholism projects funded by IHS. In 1977 there was a total of about $14 million being spent by NIAAA. In 1980, a total of $17 million will be spent by both the IHS and NIAAA.

So, while NIAAA's funding has decreased, there has been an increase in funding by the Indian Health Service.

Senator SCHMITT. Do you monitor those programs or cooperate with them?

Mr. ARCHER. We monitor them until they are transferred. In addition to that, we have an excellent working relationship with the Indian Health Service. We have a transition committee working with them. And in addition to that, we have staff within our Institute that also have been working to facilitate the transfer of these programs.

So there is a close working relationship.

TRIBE'S FINANCIAL WORKING RELATIONSHIP

Senator SCHMITT. Are the tribes themselves contributing to this program financially?

Mr. ARCHER. As far as I know, at this point in time I don't believe they are, financially.

Senator SCHMITT. Has that been discussed in any way with those tribes that have significant financial resources?

Mr. ARCHER. We've been looking into all methods of trying to get third-party payments, through health insurance, tribes, and other groups. But the major portion of the cost has had to come from both our budget and the Indian Health Service at this time. And this may well be because of other priorities in the tribes. It is a tremendous cost.

Part of our problem—and it is not unique to the Indian tribes—has been to convince communities that they need to contribute as well.

Senator SCHMITT. I understand that. That is why I asked that specific question.

Mr. ARCHER. They do contribute through the tax system.

NEW NIAAA INDIAN PROJECTS

Senator SCHMITT. Recently, the committee received a letter from HEW on the funding of Indian alcohol projects.

By the way, HEW is pronounced "hue."

While the total amount spent by HEW for Indian alcoholism projects is increasing slightly, NIAAA's proportion of this total has fallen from approximately $15 million in 1977 to $8 million in 1979.

What amount is devoted to Indian alcoholism projects in the NIAAA's 1980 budget? And you may have just given us that figure.

Mr. ARCHER. The budget amount is a total of $5,199,000. That is for 33 Indian projects specifically.

A point I would like to make is the fact that in the Secretary's initiative we're emphasizing women and youth programs. And we've already stated to the Indian groups and others that these are problems, particularly with regard to Indian women. The cirrhosis rate is 10 times as high in Indians as it is in non-Indians. The death rate is higher than in non-Indian populations.

Senator SCHMITT. But that is true throughout the whole population, isn't it, throughout the whole Indian population with alcohol-related problems?

Mr. ARCHER. Yes, the rate is higher. But it is interesting that the death rate of Indian women is as high as Indian men. Amongst non-Indian groups, the rate of cirrhosis for men is about twice as high as it is for women. Amongst Indian groups, it is almost equal. It is a much more significant problem.

Senator SCHMITT. Are you sure that is an alcohol problem? There is no other diet——

Mr. ARCHER. It may well be nutritional as well. But a major portion of it is alcohol.

Senator SCHMITT. The Indian Health Service has found in some of their other activities some diet-related and maybe some just generally ethnically related differences that have contributed to certain problems. There is an inner ear or balance problem, as I recall, with certain Indians, particularly the Navajo, that may also contribute to some of the problems with respect to alcohol.

Mr. ARCHER. It may. Even with good nutrition, heavy use of alcohol would still be the significant factor.

Senator SCHMITT. Do you feel the Indian Health Service is maturing in their own way to take pretty much primary cognizance over the Indian alcohol problems?

Mr. ARCHER. I think our effort can be phased down. It will never be phased out. I think we will always be in a position to demonstrate innovative ways to work with Indian groups. We are not planning to phase out all of our programs. We will be attempting to develop innovative ways to reach Indian women and Indian youth; we are really changing our emphasis.

Our research, for example, has indicated to us that there does appear to be a genetic factor in alcoholism. So for that reason, we

feel we can target in on specific groups of individuals—the children of alcoholics, where the rate of alcohol abuse is four times as high.

From our research, we have found we should target our prevention efforts.

Senator SCHMITT. Your letter explained, in this regard, that no new Indian alcoholism projects would be funded in 1979. Are any resources included in your 1980 request to initiate new projects?

Mr. ARCHER. Well, not specifically as Indian projects. Part of it is the problem of labels. There will be new programs of this type under "women" or under "youth," aimed at serving Indian youth and Indian women. But they will be labeled as "women" or "youth" programs.

Senator SCHMITT. So what you're telling the committee is that, rather than starting new Indian projects, you are trying to integrate these special aspects, if they are special to the Indian problems, into the other treatment programs and to make those programs somewhat broader in their application?

Mr. ARCHER. That's correct. And we're hoping, with what we've demonstrated, that the Indian Health Service itself will be developing more adequate programs for the treatment of alcoholism.

ST. ELIZABETHS HOSPITAL

Senator SCHMITT. Now, gentlemen, and particularly Dr. Pardes, we are interested in the St. Elizabeths Hospital issue. You have a statement on that subject, am I correct, Doctor?

Dr. PARDES. That is correct.

Dr. KLERMAN. Do you want to focus on St. Elizabeths?

Senator SCHMITT. We are going to ask a lot of questions for the record. We are moving toward terminating the hearing at this time. I will give you a chance to make a final statement, but we will have to do it for the record. I'm running out of time. But we will submit that statement.

[The statement follows:]

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Statement of Herbert Pardes

Mr. Chairman and Members of the Committee:

It is a pleasure to have the opportunity to appear before you to present the 1980 operating budget request for the St. Elizabeths Hospital.

The 1980 operating budget continues to reflect support for the Hospital's efforts to provide acute and rehabilitative psychiatric care to District residents and Federal beneficiaries in general, and more specifically, to support the revitalizing the St. Elizabeths Hospital. I want to report to you that we have made progress--substantial progress--towards revitalizing the Hospital and we have moved closer to the goal of integrating the Hospital into a unified and comprehensive mental health delivery system.

I would like to highlight, very briefly, activities currently underway to revitalize the Hospital.

First, the loss of accreditation is regarded as one of the most severe actions taken against a hospital; we have given the highest priority to regaining accreditation of the Hospital at the earliest possible date. All of the Hospital's deficiencies have been identified, a plan of correction for each of those deficiencies has been developed and implemented, and a system for monitoring progress has enabled us to achieve a high level of accreditation readiness. I am, therefore, pleased to report that during the month of March, 1979, we will formally request the Joint Commission on Accreditation of Hospitals to resurvey for the purpose of certifying the St. Elizabeths Hospital as an accredited institution.

Second, I am extremely pleased that the Hospital has been provided an appropriation of $52.2 million for the purpose of renovating buildings and facilities to accommodate 1,800 inpatients and to eliminate deficiencies cited by the Joint Commission; such improvements will permit the Hospital to conform with the highest standards for mental health facilities. The first major renovation, which includes eleven buildings and approximately 500 beds, is scheduled to begin with the signing of a contract on March 15, 1979.

Third, a major concern about the Hospital has been the quality of its medical and surgical services. On December 15, 1978, we contracted with the Georgetown University Hosptial to provide major medical and surgical services to St. Elizabeths' inpatients. I am pleased that we will be able to integrate the Hospital into the District's health care system and that the affiliation will be with such a prestigious institution. We believe this arrangement will significantly improve the quality of patient care.

Fourth, another issue that deeply affects the quality of life at St. Elizabeths is the matter of resettling patients in the community--ensuring that they receive care and treatment under the least restrictive conditions possible. We have launched a transitional living program to ease the

resettlement of patients into community-based living arrangements. By providing support services during a transitional period, we hope to be able to shorten the time required to return the patient fully to the community; and to minimize the possibility of rehospitalization. Intensive discussions over the past few months with District Government officials have resulted in the development of a final plan to implement the court order resulting from the Dixon v. Califano class action suit. The final plan, which describes how the District Government and the Federal Government will jointly work to deinstitutionalize patients hospitalized at St. Elizabeths, was submitted to the court on February 1, 1979.

Fifth, even more important than bricks and mortar is the quality of service to patients--here too, we can report real progress: we have instituted a formal, comprehenisve level of care survey to determine the changing needs of each patient--this gives the Hospital a much greater capacity to plan programs and services around individual patient needs; and, most importantly, to determine when patients no longer require psychiatric treatment on an inpatient basis. Another signal of growing excellence deserves special mention: the Hospital's Mental Health Program for the Deaf received the Gold Achievement Award for 1978 from the American Psychiatric Association. This award, the Association's highest achievement award, recognizes programmatic excellence and innovation.

Sixth, while all these efforts have been underway, we have been working to improve and modernize management techniques at the Hospital, to make St. Elizabeths a better place to work and a more cost-efficient operation. Management improvements already underway include streamlining the Hospital's cost control system, recentralizing some support functions, and making substantial progress in developing a management information system.

Transfer of the St. Elizabeths Hospital by 1982 remains the goal of the Department - to integrate the Hospital into a unified and comprehensive mental health delivery system managed by the District Government is the agenda item for intensive discussions held with District officials on an ongoing basis.

The 1980 operating budget totals $108,260,000 representing an increase of $6,040,000 over the 1979 level. Of the $108,260,000 requested for 1980, $23,141,000 represents anticipated reimbursements - principally from the District of Columbia - and $85,119,000 is the budget authority we are requesting for FY 1980. The requested increase covers mandatory operating costs and salary increases.

My colleagues and I will be pleased to answer any questions the Committee may have.

REGAINING ACCREDITATION

Senator SCHMITT. We would like to have your statement for the record. If you would care to tell us in summary form what progress you've made in improving the patient care at St. Elizabeths Hospital and the management of that hospital, and efforts aimed at regaining accredited status, we would like to have that at this time.

Dr. PARDES. Would you like that for the record?

Senator SCHMITT. We would like it for the record, but if you could just summarize.

Dr. PARDES. Well, I would say that we are making major progress in terms of both our administrative and clinical programs, as well as moving toward the accreditation of the hospital. I'm pleased to report that during the month of March we will formally request the Joint Commission on Accreditation of Hospitals to resurvey for the purpose of certifying the St. Elizabeths Hospital as an accredited institution.

There are a variety of other developments which I think specify those steps that we have taken, and if you are pressed for time I will hold those and simply give them to you for the record.

Senator SCHMITT. Yes, we will have that for the record.

Would you care to tell us, what are the major deficiencies at the hospital today?

Dr. PARDES. Well, I guess one would have to talk in terms of deficiencies which are in an increasing state of being addressed. For example, we are actively involved in the construction program, particularly concerned about the fire and safety codes for patients. And we are undergoing a major renovation program in order to make those buildings appropriate for such patients.

We're also actively working on the entire area of records as well as administrative organization in order to bring the hospital into an appropriate readiness point for accreditation.

So I would say those are deficiencies which we have been working on and are going to be working on continually.

Senator SCHMITT. And your budget addresses these?

PREPARED STATEMENT

Dr. PARDES. Yes, I believe it does. We have a full statement, as I say, about the variety of steps we have taken to put the hospital into good shape.

[The information follows:]

SAINT ELIZABETHS HOSPITAL

Progress Toward Accreditation

The 1973 and 1974 Joint Commission on Accreditation of Hospitals (JCAH) reports granted Saint Elizabeths Hospital one year accreditation in order that the Hospital could initiate corrective measures to enable it to gain full two year accreditation. The accreditation surveys of 1973 and 1974 were based upon the general hospital accreditation standards of the Commission as no psychiatric hospital standards had been developed. The first use of specific psychiatric hospital standards by the JCAH was in the surveys performed in 1975. The 1975 survey of Saint Elizabeths Hospital was therefore performed under new, more stringent standards provided for psychiatric hospitals. The Commission's report for 1975 stated that the Hospital was disaccredited.

Although most visible in terms of dollars, deficiencies cited by the Joint Commission on the Accreditation of Hospitals went far beyond those of the physical plant. Approximately 100 deficiencies were noted in programmatic areas. These also must be corrected if the Hospital is to achieve full accreditation. The most serious deficiencies were noted in the areas of governing body and management, medical records, environments, and staff areas. Specific steps for corrections include, but are not limited to, the following:

1. Governing Body and Management

a. A viable medical staff organization has recently been reinstituted and regular staff meetings will be held. New procedures for credentialing and assigning level of privileges to physicians, dentists, and podiatrists will be soon completed. Similar procedures for non-physician professionals are planned and will soon be implemented. The requirements for patient care audits now meet the standards. A review and update of policies and procedures will soon be completed. In order to reduce the inappropriate use of the Hospital, we are in the process of developing admission criteria to be rigorously followed in determining patient admissions to Saint Elizabeths Hospital.

b. The Hospital also is in the process of implementing what is probably one of the most comprehensive and ambitious information systems of its kind in the country. A recently completed contract resulted in the design of such a system and a current contract is implementing it. This system will integrate information about available resources (fiscal and manpower), program goals and objectives, performance standards, and service needs. The system will permit managers at all levels to plan, implement and evaluate their programs more knowledgeably and with greater accountability.

c. In response to the recommendations of the Comptroller General, functions of the Hospital are being actively reviewed for realignment on a continuum of service model. In those areas where it is explicitly indicated that centralization is required for control and effectiveness, changes will be made.

2. Medical Records

a. The Hospital has instituted a simplified four-part Medical Record which involved abolition of over 25 forms. It is felt that this will add coherence and uniformity to the record-keeping system. Updated guidelines for the patient treatment plan and a revision of the case study are being implemented.

b. The Hospital has instituted a concurrent review process through which the documentation of each patient entering the Hospital is reviewed for the appropriateness of the admission, the adequacy of the documentation, the timeliness of the documentation, the adequacy of the treatment plan and feedback mechanism for cited deficiencies. This review is adapted from the Professional Standards Review Organization format which is more comprehensive.

c. The Hospital has undertaken an internal review of records; each clinical division has instituted an ongoing review of records, and the Hospital has undertaken a contract to review accreditation readiness, including the medical record.

d. In order to improve access to records, a procedure has been established whereby the record of a discharged patient on readmission up to five years past discharge is immediately available to the physician.

e. During 1979 there will be further reorganization to place Medical Records, the Registrar and the Central Admission Service in physical proximity for greater coordination and improved work flow. Two changes have been made in response to deficiencies noted by the Joint Commission in 1975: records of discharged patients are to be completed within 12 days after discharge, and treatment planning is to be done by a multi-disciplinary team.

3. Physical Plant

The Congressional allocation will bring currently utilized buildings into a minimal compliance with the life safety code. A master plan for renovation has been developed and approved, and is on schedule. In brief, the plan calls for the renovation of approximately 1,800 beds for an effective use of 20 years, life safety improvements for approximately 500 short-term beds (5 years) are planned to be used during the renovation period, and improvement in the life safety support systems (power plant, shops, etc.). It is anticipated that the total renovation will require approximately 4 years. Both the Joint Commission on the Accreditation of Hospitals and the General Accounting Office have cited as a deficiency the inability of the Hospital's facilities to meet the National Fire Protection Association's Life Safety Code Standards. From the point of view of the Joint Commission, it is our greatest single need and the one which the Congressional allocation will correct.

a. Environment and Safety

(1) The environmental and safety deficiencies will require the completion of the renovations made possible by the Congressional

appropriation. Other improvements are possible with existing resources. The Hospital has undertaken a program of frequent inspections, and is in the process of streamlining its response mechanism. Some specific actions taken by the Hospital since the last accreditation survey include: installation of an autonomous emergency power source to provide necessary lighting for the safety of patients and personnel; installation of an electrically supervised, manually operated fire alarm system that transmits an alarm automatically to the Saint Elizabeths Hospital's fire station; installation of fire resistive doors; the Disaster Plan has been revised and drills held; supervised fire drills are held regularly; overcrowding has been reduced.

(2) All patient areas now have drapes and interior decoration, and there have been increased efforts to personalize clothing and personal spaces. Recently instituted activities include a systems approach to environmental and safety monitoring which includes the full range of concerns from functional safety and sanitation to some aspects of ward administration and the psychosocial environment.

b. Reduction of Overcrowding

Since the last accreditation survey, the resident population has been reduced by 800 patients. This reduction (which has been factored into the long-term construction plans) has already resulted in a measurable reduction in overcrowding.

4. Staffing

Marked improvement has been made in more uniform staff coverage and the scheduling of activities. Additional nursing staff has been assigned for evening and weekend coverage, and there are active recruitment efforts underway to attract additional registered nurses. The central admission service now has 15 full and part-time psychiatrists and has increased its services to include a greater variety of services (social work services; crisis intervention without admission) to more patients and potential patients. Staff has been made available to increase recreational activities on evenings and weekends which has added further opportunities for patients to participate in a variety of programs.

Additional clinical dietitians are permitting greater participation by dietary personnel in treatment planning, patient education, and outplacement monitoring. Current plans call for a move to the unit dose system and decentralized pharmacy service. Toward this end, additional pharmacy personnel have been and are being recruited.

A program has been instituted to assure that every noted deficiency is addressed. Responsibility for monitoring correction has been assigned, and steps have been taken organizationally to achieve compliance in all areas.

Other Improvements

At the time of the last survey, the Division of Medical and Surgical Support Programs was found to be accreditable despite the fact that the parent organization was not in compliance. However, to further improve service, the Hospital has recently entered into a contract with Georgetown University Hospital for the purpose of effecting a higher quality of care for our major medical and surgical patients.

The Area D Community Mental Health Center is currently accredited as of December 1977, and was reviewed by the JCAH during the month of January 1979 for continuing accreditation, under the standards for Community Mental Health Service Programs. A Division of Child and Adolescent services was recently established which will be reviewed using the JCAH Children and Adolescent standards for such services. At the time of the last review, young patients were scattered throughout the Hospital and the program did not meet the JCAH Standards. Services to alcoholics were similarly dispersed although patients with alcohol and alcohol related problems continued to be served by all divisions. Identified alcoholism programs have been consolidated into two services, one was reviewed as part of the Area D Community Mental Health Center and the other to be reviewed under the specialized JCAH Standards for Alcoholism Programs.

The Hospital has launched a transitional living program to ease the resettlement of patients into community-based living arrangements. By providing support services during a transitional period, we expect to shorten the time required to return the patient fully to the community; and to minimize the possiblity of rehospitalization.

Intensive discussions over the past few months with District Government officials have resulted in the development of a final plan to implement the Court Order relating to the Dixon v. Califano class action suit. The final plan, which describes how the District Government and the Federal Government will jointly work to deinstitutionalize patients hospitalized at Saint Elizabeths, was submitted to the court on February 1, 1979.

We have instituted a formal, comprehensive level of care survey to determine the changing needs of each patient -- this gives the Hospital a much greater capacity to plan programs and services around individual patient needs; and, most importantly, to determine when patients no longer require psychiatric treatment on an inpatient basis.

The Hospital's Mental Health Program for the Deaf received the Gold Achievement Award for 1978 from the American Psychiatric Association. This award, the Association's highest achievement award, recognizes progammatic excellence and innovation.

Management improvements now underway include streamlining the Hospital's cost control system, recentralizing some support functions, and making substantial progress in developing a management information system.

EFFECT OF FEDERAL PROGRAMS ON MENTAL HEALTH

Senator SCHMITT. I have two questions for the record that are more philosophical than anything else, that I personally would like you to consider, Doctor, and to consider them in half a page or more, depending upon your inclination.

One is the effect of—how shall I phrase this best?—the effect of the major funding programs in the Federal Government on mental health. And I might ask you to look up what Aristotle had to say about the family, that the family is an institution designed to satisfy everyday wants, and we have introduced into our social structure a fairly large governmental presence for satisfying everyday wants in major portions of our society. And I would just like to have your thoughts on what the impact of this has been on mental health, as you view it. And maybe you will say it has been a positive impact. I will be curious to see that.

[The information follows:]

In both a real and symbolic sense, Federal funds mean a Federal presence in the affairs of the beneficiary. When the primary recipient is another governmental body or a nonprofit organization, the individual is still the ultimate beneficiary. As a result, the individual may have to surrender some degrees of freedom as a condition for receiving Federal assistance. On the other hand, the Federal funding programs often represent an act of compassion of a society for people who would secure no attention or help from other sectors.

In many respects, and for several economically deprived sectors of the population, Government may assume functions that traditionally have been part of the role of the family. Along with this role it inherits a variety of potential liabilities. While the Federal presence may be the only hope for some people, it may also be seen as potentially intrusive or uncaring, and therefore evoke hostility. It may, if it is lax or gullible in the administration of its programs, encourage individuals to become overly dependent or adept at manipulating the system. If it treats symptoms rather than causes, it can prolong the problems it seeks to cure, while accumulating new ones. Thus one cannot speak solely of too much or too little government, but one must attend to the matter of the appropriateness and common sense of the individual Federal program.

Reference was made to the family which, as Aristotle said, is an institution designed to satisfy everday wants. Our own mental health research on traditional and alternative mental health care systems supports Aristotle's view of the importance of the family. It also indicates that no substitute government care is particularly satisfactory for the individual cared for. Consequently, our research and intervention efforts are aimed at learning how the family can be supported in its role of supporting its own members. Mental health services are often designed to develop a greater sense of independence and autonomy by individual people in their own lives. We also study the family in relation to the work place and explore ways by which more flexible work arrangements can enable the worker to be more supportive of his or her family. This latter point is particularly important, since in the event that families disintegrate, the need for some outside (and often governmental) presence and support becomes necessary by default.

To summarize, the Government has a responsibility to step in when the individual is overwhelmed by circumstances beyond either his control or that of his family. At that point, the Government also incurs a responsibility to invervene sensibly and realistically, in a manner which will return the individual to an independently functioning State as quickly as possible. There are, however, those individuals who will likely never return to full independence and who require sustained support. The Government, by developing programs which aim at maximizing the degree of functioning of such an individual, for investigating ways by which it can enhance and increase that independence, and by responding compassionately to individuals with either acute or chronic needs, can play a most important role in enhancing the mental health of the citizens.

Therefore, what is the impact on mental health of the Federal presence? The answer is that is probably at times critical, at times enormously supportive, at times

not as good as it could be, and probably beneficial and supportive to the degree that it is sensitive to the specific problem and need.

TECHNOLOGY TRANSFER

Senator SCHMITT. Also, I'm curious whether—and I ask this question of all people related to the medical profession—have you, from your perspective of mental health and alcohol and drug abuse, looked at, carefully, the results of NASA's biomedical programs in research to see what technology transfer is possible and might be appropriate for short- and long-term examination?

So I will let you answer those questions for the record.

[The information follows:]

The National Institue on Drug Abuse has consulted with NASA on the transfer of technology directly and is currently reviewing a grant application which proposes to study social and behavior factors in a controlled environment developed under contract to NASA. Also, a number of innovative experimental procedures originally developed by NASA-sponsored scientists is currently being utilized by researchers studying the factors which control drug seeking behavior.

Staff members of NIDA's Division of Research have contacted the Director of NASA's Life Sciences Program to discuss the measurement of physiological concomitants of drug seeking behavior and withdrawal. A NASA biomedical telemetry engineer met with NIDA scientists and discussed the various types of telemetry devices that NASA had available to remotely measure and monitor human physiological status (heart rate, blood pressure, pulse rate, body temperature, etc.).

In a general and significant way, behavioral research sponsored by NASA has helped develop the whole technology of drug self-administration methods. Scientists at the University of Maryland used NASA developed facilities back in the early 1960's to develop animal models of drug seeking behavior and intravenous administration of drugs of abuse. This early work contributed significantly to the development of a standard methodology now endorsed by the World Health Organization to test the abuse liability of drugs.

The National Institute of Mental Health is not currently involved in any research of NASA concern. In the early stages of the space program there was some limited overlap of research interests between NIMH and NASA in areas of human perception and decision-making. However, as the programs of these two agencies have grown, common areas of scientific investigation have lessened.

The National Institute on Alcohol Abuse and Alcoholism has not approached NASA to date, but identifies several areas of potential interagency collaboration. One such example is a monitoring device developed by the Goddard Space Flight Center which may be helpful in measuring blood alcohol concentration or other fetal characteristics in research on the effects of maternal alcohol consumption.

Another area of potential technology transfer is NASA research on how the human nervous system operates under specific conditions in space. NASA findings may be of assistance in developing strategies for rehabilitation of alocoholic persons in that an understanding of factors such as isolation, memory functioning, and physiological changes in space may lead to the development and/or enhancement of treatment techniques for alcoholic persons.

The neurological and control concepts developed by NASA through its work in robotics may be helpful in understanding the function of the brain in its control process in alcoholism. This knowledge could lead to a better understanding of the functioning of the alcoholic and therefore have implications for improved rehabilitation strategies.

QUESTIONS SUBMITTED FOR RESPONSES

Senator SCHMITT. Now, do you have any final comment?

Dr. KLERMAN. I want to say for myself, I think this has been a vigorous exchange, and your background as a scientist comes through in your questioning.

Senator SCHMITT. Well, I could stay here for 2 more hours if I did not have to worry about Indian education. But that is important also, and maybe that is one way that we can solve your problems.

The questions for the record should be here, hopefully, within 7 days, if that can be done. And also, your edited version of the transcript in that time frame.

[The following questions were not asked at the hearing, but were submitted to the Department for response subsequent to the hearing:]

MENTAL HEALTH RESEARCH - DIABETES

Question: Dr. Klerman, did your Agency undertake research into the mental and emotional problems of families living with Diabetes in 1979?

Answer: The Institute has undertaken a number of activities in both its intramural and extramural research programs. Staff of both programs took part in a recent workshop on the behavioral and psychosocial aspects of diabetes, convened by the National Institute of Arthritis, Metabolism and Disgestive Diseases and the National Diabetes Advisory Board. It made preliminary recommendations on areas of needed research and began planning for a conference to build a national research agenda. NIMH will help support that conference and NIMH staff are helping plan it. A senior research scientist has been added to the staff of the Institute's Laboratory of Developmental Psychology, has assembled a research team, and has begun a program of research on the range of behavioral reactions and coping skills used by children with juvenile diabetes, and on the medical and psychological factors contributing to the illness. The findings of this research on behavioral patterns associated with juvenile diabetes should generalize to the behavior elicited by other stress situations experienced by children in the course of normal development, and should add to our understanding of how families either facilitate or impede the child's competence in dealing with a range of personal challenges that are inherent in daily living and in the growth process. NIMH and four NIH research institutes are issuing a joint announcement requesting applications for research on the behavioral aspects of diabetes mellitus. NIMH has already made one award to an investigator at the Philadelphia Child Guidance Clinic, for a study of Family Mental Health Factors in Juvenile Diabetes. The project is to study relationships between family organization and the psychological and medical adaptation of juvenile diabetics and their families.

Question: What amount of resources was devoted to this problem in 1979 and what is included in your 1980 budget request for this effort?

Answer: We set aside a total of $400,000 in 1979, and spent $220,000 of this amount to date. We expect to spend the full amount by the end of the year. In 1980, we expect to continue our current efforts at the $400,000 level, as well as encourage additional grant applications of scientific merit.

AFTERCARE

Question: Last year's hearings brought out a major concern towards the needs of our Senior Citizens. To be more specific, the concept of "Aftercare" of patients was addressed in great length. Dr. Butler and Dr. Klerman both assured this Committee that: first, there would be an increase in funds for mental disorder research towards the elderly; and second an intramural research program for a special program on mental conditions of the aged would be established. What has been done in regard to both these points? Have these programs realized any results as of yet?

Answer: In 1979, we increased our allocations for research on mental health of the aging by 55 percent - from $4.0 million to $6.2 million. With these additional funds, we are supporting research projects on the origin and diagnosis and treatment of mental disorders among the elderly. Specifically, these projects address memory function, depression, dementia, and effects of major life changes such as widowhood and illness. Programs are also being funded in services research and prevention. The intramural research program on psychoses of the elderly is not yet operational. In order to be in conformance with the provisions of the Civil Service Reform Act requiring that Federal employment be maintained at the September 1977 on-board level, the Institute has been provided an employment ceiling of 5 percent below budgeted positions. Since we were in excess of the ceiling at the time of its imposition, new positions have been most accutely affected and, therefore, recruitment for the 40 new positions authorized for this program has been delayed.

ORGANIC BRAIN DISEASE IN THE ELDERLY

Question: Last year the Committee directed that an expanded program in conjunction with the appropriate Institutes at NIH be implemented to study the problems of organic brain disease in the elderly. What has been done in response to this directive?

Answer: The National Institute of Mental Health in collaboration with the National Institute on Aging and the National Institute of Neurological and Communicative Diseases and Stroke held a conference on "The Clinical Aspects of Alzheimer's Disease" in December 1978. This conference consolidated information on these diseases, reviewed treatment and management modalities, examined service delivery systems, and recommended research directions. A report will be published on the results. NINCDS, which is carrying out epidemiological studies on the incidence and prevalence of senile dementia, has consulted with NIMH. NIMH is studying the epidemiology of mental disorders in the community for all ages. The part of the research that is on the aged is being funded jointly by NIMH and NIA. The NIMH in general has been active in stimulating new research proposals concerning organic brain disorders in the elderly and sees this as high priority.

Question: Please explain the program, its objectives, projected costs and its headway in the field of organic brain disorders.

Answer: In fiscal year 1978, NIMH invested $1.1 million in extramural research on organic brain disease. While it is still too early to determine the amount of headway that has been made, the quality of the research proposals funded is promising. The approach has been to focus upon several important research questions relating to the identification and treatment of altered brain function in late life. In the NIMH extramural program, several research projects are of interest. One project is examining the relationship between structural damage to the brain and disordered behavior in the early stages of senescent brain disease. Another is looking at the interface between anatomical and electrophysiological changes in the brain and ability for self-care in the community. The diagnostic effectiveness of new, high technology devices is being evaluated, and new treatment methods are being studied. Both behavioral and pharmacological techniques are being used in efforts to reduce or halt the progressive intellectual disabilities which accompany the various states of altered brain function in old age. It is anticipated that these projects will yield rich sources of information which can be utilized by primary and secondary care providers. The results will enhance the ability of the clinician to identify, diagnose, and treat the organic brain diseases of late life.

HUNTINGTON'S DISEASE

Question: What is being done by NIMH to implement the recommendations of the Huntington's Disease Commission?

Answer: Work has begun on an instructional course dealing with Huntington's Disease, Altzheimer's Syndrome and Parkinson's Disease. Course material is aimed at CMHC staff and others in the health service area who may come in contact with these types of patients. One of the goals of the proposed course is to make such health care personnel aware of the early manifestations of these illnesses and that some patient behaviors may represent symptoms of these neurological disorders. NIMH staff and staff of the National Institute of Neurological and Communicative Diseases and Stroke have worked jointly on the preliminary phases of this project.

EMPHASIS ON EPIDEMIOLOGY

Question: Your plans include stepping up efforts in the area of Epidemiology research to learn more about the extent of mental illness. How many Epidemiologists do you envision will be needed?

Answer: Based upon estimates obtained from expert psychiatric epidemiologists NIMH estimates that the total present national need for career psychiatric epidemiologists is approximately 130, or roughly four times the present number. This would permit averages of one position each in most schools of public health, half of the departments of psychiatry in the medical schools, most of the sociology and psychology departments in the larger universities with schools of public health, and in one State department of mental hygiene for each of the ten health regions.

Question: Is there a ready supply of such specialists -- or do you intend to fill the need through on-the-job training?

Answer: There are only approximately 35 career psychiatric epidemiologists in the country. Most of these individuals have an M.D. degree, but a few have doctorates in sociology or psychology, and all of them have spent the majority of their professional careers in this specific subdiscipline. There are several hundred others with similar professional degrees, who do psychiatric epidemiologic research from time to time, but whose primary identity is with another field. Because the discipline is so new, only a handful of either group have received formal training in psychiatric epidemiology. In summary, there is not a ready supply of specialists. While on-the-job training would undoubtedly develop a few more specialists, it would not suffice to bring others into the field.

DRUGS

Question: As part of your "Major Mental Illnesses" research effort, you plan to "assess the relative effectiveness of various drug therapies," etc. Do you do any drug development on your own? Do you contract or consult with the major drug houses on this?

Answer: There is no formal drug development or drug screening activity like that carried out by the National Cancer Institute. However, through the Public Health Service research grant mechanism, studies have been supported on development of methods for preclinical screening and techniques for clinical drug assessment. There is no active contract or consultation program with the pharmaceutical industry but scientific staff from the pharmaceutical industry discuss technical problems of mutual concern with NIMH staff. These discussions occur at scientific meetings, sometimes at NIMH headquarters, or at government-sponsored conferences such as the Annual New Clinical Drug Evaluation Unit meeting, sponsored by the NIMH.

INCREASED STATE SUPPORT

Question: Have any efforts been made to develop guidelines for providing Federal incentives to stimulate increased State support of research activities in mental health and related areas (as recommended by the President's Commission on Mental Health)?

Answer: The issue was taken before the NIMH National Advisory Mental Health Council in December 1978. The Council gave general support for an increased State research capacity, but did not resolve questions about the scope of research to be encouraged at the State level and about the appropriate role for the NIMH. Within the Institute, staff most involved with State mental health programs have been consulted extensively, and in early February an advisory meeting was held with all Division Directors and heads of relevant research and service components. To maintain liaison with State interests, the Institute maintains an active working relationship with the State Mental Health Research Directors Division of the National Association of State Mental Health Program Directors. During the course of these activities, two issues have remained central concerns: first, the kind of research to be fostered, and second the nature and range of possible Federal incentives. In the first instance, there is a consensus that States have a unique role

in carrying out research on service delivery systems, and that NIMH should encourage this capability rather than encourage a broad interest in all mental health research -- basic, social, behavioral, and clinical. The wide variations in State research interests, programs, and capacities further necessitates a specific approach. On the issue of potential Federal incentives, there is a need to investigate, define, and pursue existing mechanisms and funding sources for Federal-State interactions, especially in the area of service delivery research, before thought is given to developing new mechanisms which might serve as Federal incentives. The NIMH plans to focus on this activity during the remainder of this fiscal year.

MENTAL HEALTH TRAINING

Question: Last year's committee report emphasized the importance of training to deal with the needs of special groups, such as the elderly, children, adolescents and minorities. What have you done to be responsive to this Committee concern?

Answer: In 1979, NIMH increased the level of clinical training funding for the elderly by $1,195,000 or 75 percent over the 1978 level; support for child and adolescent oriented training increased by $927,000 or 12 percent; and minority mental health training programs increased by $1,378,000 or 15 percent. Beginning in 1980, in response to the concerns of the Committee and the President's Commission on Mental Health, NIMH will award training grants only to programs that meet the needs of underserved populations. Education to provide service to children and adolescents, the elderly and minorities is of the highest priority in the new program.

Questions: What have you done to deal with shortages of trained personnel in rural and inner-city areas?

Answer: The problem is being approached in several ways. First, we are encouraging changes in the basic training of the professional disciplines by awarding grants only to those programs which focus on preparation for service of underserved populations. This includes the development of new programs in rural and inner city areas, and the extension of existing programs to these locations. Services to these groups are provided as a part of training. Second, we are seeking legislative authority to require a service payback in shortage areas from students who receive NIMH support for their basic professional education. Acceptable locations for payback will for the most part, be facilities in underserved rural and inner city areas. The third strategy is one of aid to the states and regions for the development of a comprehensive manpower plan. This plan will include recruitment, training, continuing education, and retention of personnel in underserved areas and understaffed facilities. Fourth, NIMH provides funds for the training of primary and general health care givers in mental health knowledge and skills, so that people residing in areas with little or no specialized mental health services can receive help. Fifth, NIMH is increasing its research efforts on manpower to discover and promote new solutions to the problems of maldistribution, to aid in recruitment and retention of professionals in shortage areas, and to provide services by new categories of personnel.

Question: You have requested decreased resources in 1980 for clinical training. Have the States shown any progress in increasing their roles in this area?

Answer: There is no appreciable increase in State roles yet. However, NIMH makes awards to States for planning and demonstration projects in manpower development. Through these awards, the States are becoming more aware of manpower problems, and of more efficient and innovative ways to address them.

MENTAL HEALTH PERSONNEL

Question: Is there a shortage of psychiatrists or of other mental health personnel? If there is, what should be done about it?

Answer: There is moderate shortage for the non-medical disciplines; however, the situation is worse for psychiatry. In the non-medical area, the NIMH policy is not to greatly increase the supply, but to influence training to make the programs more responsive to national service delivery needs. These efforts would include a payback provision through a period of service in facilities and areas where there is a shortage of these professions. In psychiatry, there are shortages in many geographic areas and mental health facilities. Two thirds of the counties in the United States have no psychiatrist; many state hospitals and community mental health centers have too few on their staffs. Psychiatry has tended to rely on foreign medical graduates, with the result that over half of the psychiatric and other medical staff of State hospitals are foreign medical graduates. The number of American medical graduates entering psychiatric residency training has been dropping since 1970. With new restrictions on the entrance of foreign trained physicians into the country, the situation will rapidly become worse. The Mental Health training proposals for 1980 take account of the special problems of psychiatry in several ways: First, the proposed number of new and competing awards in the psychiatry area will be doubled - from 83 in 1979 to 188 in 1980. Second, the proposed mental health service payback programs proposed for most mental health disciplines will not be applied to psychiatry, since many psychiatric residents will already have incurred a service payback obligation in the National Health Service Corps from receipt of support during medical school. NIMH plans to terminate all stipend support for basic residency training in psychiatry. For this particular specialty, other funding sources exist. This will enable NIMH to further increase its investment in institutional support. Third, NIMH is proposing a $2.4 million new initiative which will provide 39 new awards in the area of primary care. By providing psychiatric and related mental health training to primary care physicians, much of the current demand for psychiatric services can be handled at the primary care level. Fourth, we will do all we can to encourage medical schools to accept students interested in psychiatry, maintain their psychiatric residency positions, and encourage medical students to enter this specialty. Finally, the National Health Service Corps has agreed to intensify its own efforts to take more students into psychiatry.

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PROJECTED SHORTAGES FOR MENTAL HEALTH PROFESSIONALS

Question: Please provide for the record the shortages you are projecting for fiscal 1980 in the following professional categories: psychiatrists, clinical psychologists, psychiatric social workers, and psychiatric nurses.

Answer: The following statement and table sets forth the information requested, and provides the basis for the estimates. Information for 1985 is also included, in order to establish trend data.

Supply and Demand for Mental Health Professionals

It is estimated that in 1980, as well as the forseeable future, there will continue to be a shortage of psychiatrists, clinical psychologists, psychiatric social workers, and psychiatric nurses. There are approximately 193,000 other mental health professional and paraprofessional workers currently employed in mental health facilities. It is difficult to assess future supply and demand for these latter groups, due to the varied nature of their training and employment.

The following table sets forth the most recent available data (1975) on the current supply of core discipline professionals. Supply and demand are then projected for 1980 and 1985. The 1975 data assumes a 2.5 percent utilization rate by the national population. The rate is derived from studies of the number of patients seen, as well as treatment episodes in mental health facilities. It includes only that portion of the population with serious mental illness requiring specialized professional care, and is limited by the number of mental health professionals available. It is also impacted by the degree to which primary health care providers may not recognize mental health problems, and therefore not refer some patients to treatment in a mental health setting.

Data on Availability and Demand

	Psychiatrists	Clinical Psychologists	Psychiatric Social Workers	Psychiatric Nurses
I. 1975 Data - 2.5% Utilization:				
Available supply	26,500	21,000	21,000	38,000
II. 1980 Projection - Assuming 3.5% Utilization:				
A. Est. Demand...	38,900	30,800	30,800	46,900
B. Est. Supply...	28,800	24,200	26,400	43,500
C. Est. Shortfall	10,100	6,600	4,400	3,400
III. 1985 Projection - Assuming 3.5% Utilization:				
A. Est. Demand...	40,900	32,300	32,300	48,400
B. Est. Supply...	30,000	28,500	30,400	47,600
C. Est. Shortfall	10,900	3,800	1,900	800

The 1980 and 1985 data assume a 3.5 percent utilization rate. This is a conservative projection, in view of a continued rise in the utilization of psychiatric services and the prevalence of mental disorders in the population. It assumes some expansion in the number of community mental health centers, and is applied against Census Bureau Series "E" estimates, which assume low population growth to 224 million in 1980 and 236 million in 1985. In fact, a more realistic estimate would point to a 3.75 -4.00 percent utilization rate.

The supply estimates project current production rates, adjusted for minimal rates of attrition from the existing manpower pool. Production has dropped sharply for psychiatrists, because of limitations placed on the number of foreign medical graduates entering the country or undertaking psychiatric residency training. The numbers also reflect declines in the number of U.S. medical graduates entering psychiatric residency. Estimates of the number of available psychiatrists includes the number of residents in training, as well as those in actual practice. The numbers of available psychiatrists are somewhat lower than previously reported estimates, due to the availability of more recent source data.

The data for psychiatric nurses reflects some shift in employment from inpatient mental health facilities to health maintenance organizations, emergency facilities, community mental health centers, and nursing homes providing care for the aged who are mentally ill. The increase in demand for psychiatric nurses is not as great as in other professions because nurses are predominantly employed by inpatient facilities, whereas new demand is mainly for outpatient personnel.

If the nation is to maintain the same ratio of professionals to clients as existed in 1975, we will - in 1980 - require an additional 10,100 psychiatrists, 6,600 psychologists, 4,400 psychiatric social workers, and 3,400 psychiatric nurses. The demand is caused primarily by a rising utilization rate. The shortfall drops for the three non-medical mental health professions. It worsens for psychiatrists because of declines in the supply of both U.S. and foreign medical graduates.

It should be noted that the existing supply of mental health professionals is not equitably distributed, and shortages are much worse in some geographic areas and types of mental health facilities than others. Accordingly, NIMH is requesting authorizations to require that those students in the mental health professions who receive NIMH support for their basic education later work for a period of time in shortage areas or with underserved populations. While NIMH provides stipends to only a fraction of all professional students, the payback requirement should make a real impact on maldistribution. Over 3,200 job vacancies in understaffed public facilities have been identified in a recent survey. At the same time because of the shortage of new psychiatrists NIMH must support projects which will make specialization in psychiatry a more attractive career choice for American medical graduates, as well as projects designed to give greater mental health skills and knowledge to primary care physicians so that they can better handle some of the demand for psychiatric services.

PAYBACK REQUIREMENT

Question: How will your proposed system of requiring a service payback from students receiving NIMH support work?

Answer: The proposed payback system will be modeled after the one used under the National Research Service Award Act. Traineeships would be awarded through institutional grants to academic programs focusing on priority areas identified by the President's Commission on Mental Health (PCMH). Thus there would be an assurance that students were educated in a program of high quality which emphasized national needs. Priority in the awarding of stipends would be given to minority and other disadvantaged students, and the universities would be so notified. Students receiving support would be recruited by the universities but would sign an agreement with NIMH to work after graduation in a geographic area or facility meeting the shortage criteria developed by NIMH. A year of service would be required for each year of support, and stipends would be approximately $4,000 - $6,000 per year, plus tuition. Students could "buy out" by refunding 3 times the full amount received, plus interest, within one year of default. Criteria for acceptable post-training employment which meets the needs specified by the PCMH will be developed by NIMH in collaboration with HRA, HSA, State mental health agencies and professional associations. Students, who traditionally work in mental health facilities, would be expected to find their own jobs, meeting NIMH criteria, after graduation. NIMH would not place the student or develop the site. The employing agency or facility, not the Federal Government, would pay the salary of the trainee during the payback period, although service in the National Health Service Corps would be an available option. The number of traineeships awarded in each discipline will be a function of the continuing need for that category of personnel. This need will be determined not only by the ease which students have in finding positions in shortage areas or settings but also by special studies and research projects. Payback will not be required from paraprofessional students, from anyone receiving support in short term programs (less than six months), or from students in experimental, innovative, or liaison programs not considered established basic professional education, or from those receiving specialized training beyond the basic training in areas of high priority.

Question: How is it tied to NIMH service delivery programs?

Answer: In developing criteria for locations acceptable for service payback, priority will be given to facilities funded under the NIMH new services initiatives grants, as these will be in areas where few or no mental health services presently exist, and where there is a shortage of manpower. As these facilities would otherwise have trouble attracting qualified staff, the payback mechanism will be crucial in assuring the quality of care and the success of the new program. Other acceptable locations will include health facilities supported by linkage grants or those funded by the Health Services Administration, understaffed community mental health centers, State mental hospitals, and other public facilities, especially those serving the needs of children, the elderly, or minorities.

Question: Will all obligated students be required to work in underserved geographic areas, or can other manpower needs be met through this system?

Answer: Most students will be required to work in underserved geographic areas, understaffed facilities such as state mental hospitals, or with special populations such as children, the elderly, minorities, or those involved with the criminal justice system. In a limited number of special cases the purpose of training - as specified before the funds are awarded - will be to meet the shortage of career teachers, administrators, etc. in a given category. In these instances payback requirements will be consistent with the purpose of the award. An example of this might be the need to produce highly qualified specialists to set up programs to train students in ways to recognize and treat the special mental health problems of the elderly.

Question: Why have you adopted this model, rather than that of the National Health Service Corps?

Answer: The proposed payback program is modeled after that of the National Research Services Awards (NRSA) Act, rather than after the National Health Service Corps (NHSC) for several reasons: First, direct recruitment of students by the Government as in the NHSC entails added costs and does not allow for consideration and evaluation of the specific training program. Second under NHSC legislation, only 10% of all scholarships may be awarded to non-medical or non-dental students, a number far too low to meet the needs for mental health personnel. Third, post-training site development, placement and salary costs to the Federal Government are extremely high in the NHSC, and would not be incurred under the NIMH plan. Fourth, while physicians and dentists commonly work in private practice settings, the mental health disciplines to be supported are employed predominantly by organized care facilities, and it is thus appropriate that they fulfill their payback obligation in these settings, with their salaries paid by the employing agency or facility. Finally the use of already established positions will make measurement of need closer to actual demand for services, and will allow for assessment of progress in meeting these needs.

SERVICES TO CHILDREN AND ELDERLY

Question: What are you doing to train people to provide better mental health care to children and the elderly?

Answer: In 1978, NIMH spent $1.6 million to train people to provide services to the elderly, and $7.7 million in training programs for children and youth. These funding levels increased in 1979 to $2.8 million and $8.6 million for the elderly and for children respectively. Supported programs fall into three general areas: those to train specialists in the core professions who will spend their time solely on the mental health needs of children or the elderly; those to provide extra training on the problems of these age groups as part of the basic education of mental health professionals; and continuing or supplemental education in these areas for professionals and paraprofessionals already working in mental health facilities. Through a reduction in general professional education, the 1980 programs for children and the elderly will continue to be funded at the 1979 level.

CLINICAL TRAINING

Question: To what extent have the recommendations of the Senate Report accompanying the FY 1979 Appropriations for NIMH clinical manpower training been implemented?

Answer: The Senate Report recommended an increase of $11 million over the President's budget request, to be used for training of mental health professionals who are committed to practicing in public service settings, especially community mental health centers. Among the priority areas emphasized were state manpower development and underserved geographic areas and population groups such as children, adolescents, the elderly, and minorities. Primary care was also an area of emphasis. The amount of the increase was reduced to $6 million in the Conference allowance. However, NIMH added $2.1 million in funds redirected from general professional education and thereby applied a total 1979 increase of $8.1 million to the Senate priorities. Of this increase, $1.2 million was used for primary care; $0.9 million was applied to children and adolescents; $1.2 million has been allocated to programs for the elderly; $1.4 million was directed to minority programs; $2.4 million is being applied to training related to service in underserved areas; and $1.0 million has been allocated to state manpower development.

Question: Do you believe there are adequate numbers of psychiatrists and other trained mental health personnel to meet the needs for the services stimulated by your special initiatives to develop a nationwide community mental health system?

Answer: The current supply and rate of production in the non-psychiatric mental health specialties, although improved, is not quite adequate in terms of total numbers; also, there will need to be a significant redistribution of new graduates into public service settings, and into the treatment of underserved population groups - as well as underserved geographic areas. In psychiatry, there are problems of both inadequate supply and maldistribution. The supply problem is the product of two factors: declining numbers of U.S. medical graduates entering psychiatric residency training, and more stringent restrictions upon the entry of foreign medical graduates into the United States. The latter group was relied upon heavily to compensate for shortages of psychiatrists in state psychiatric hospital facilities.

Question: Last year, the Congress appropriated $6 million above the President's request for NIMH clinical manpower training based upon compelling testimony underlining the need for such trained personnel. We note that for FY 1980, you have requested that such appropriations be reduced to the FY 1978 level -- $68,263 million. In view of apparent inconsistency between utilization of your full Congressional appropriation for FY 1979 and your request for FY 1980, could you explain the reasoning behind your reduced request for this coming fiscal year? Have you been able to meet all unmet service needs identified in the President's Commission on Mental Health report and last year's Senate report?

Answer: We have not yet met all of the service needs identified by the Congress and PCMH, although the 1979 Congressional increase provided a major step in that direction. The 1980 request is actually $70,663,000. It represents what is felt to be a reasonable compromise between the constraints of limited resources and the need for continued redirection of the training program. The request provides a $2.4 million new initiative for primary care, while maintaining the other clinical training programs at the $68,263,000 dollar level as appropriated for 1978 and originally requested in the 1979 President's budget. The momentum of the redirection has been largely maintained at the 1979 level, by taking a major portion of the 1980 decrease from general professional education.

TRAINING FOR SERVICES TO THE UNDERSERVED

Question: What assurances can you give us that psychiatrists and that other personnel supported by clinical manpower training appropriations will provide services to the underserved and inappropriately served as identified in the PCMH as in need of treatment for mental illness?

Answer: For 1980, guidelines for awarding of training grants will specify that programs must either focus on a single service delivery priority or address in a significant manner at least two major priority areas. These include children and youth, elderly, minorities, preparation for work in underserved areas or public facilities, work with the primary health care system, and, to a lesser extent, prevention and mental health services to the criminal justice system. These areas have been priorities for several years, and changes in support of training have occurred. The NIMH now plans complete redirection, and will no longer award grants merely for support of basic professional education. The old program will be phased out as present grants terminate. Educational institutions will specify in their applications which priorities they propose to address, what percentage of awarded funds will go to each priority, and how these funds will be spent. Grantees will be expected to indicate the nature and extent of collaboration with service delivery organizations and, where appropriate, the State mental health authority. In recognition of the shortage of professionals in many geographic areas and service settings, we will propose that students receiving Federal support for training be obligated to repay their support through service in shortage areas. A NIMH payback program would not apply to psychiatric residents as other non-Federal sources of support are available, including those the institution receives for delivery of services. In addition, many psychiatric residents will already have incurred a service payback obligation in the National Health Service Corps from receipt of support during medical school. An attempt to impose additional payback requirements on this one medical specialty would be a disincentive to enter psychiatric training, and in any case few residents would accept under these conditions as they have other options. Since requiring payback is not feasible at the residency level, NIMH plans to terminate all stipend support for basic residency training in psychiatry.

ROLE OF PRIMARY CARE PHYSICIAN

Question: What do you see as the role of primary care physicians in delivering mental health services, and what are you doing to prepare them to give better care to the mentally ill?

Answer: Mental health specialists see only 25 percent of those with mental health problems. The majority of the remaining 75 percent are seen in the general health field. It is therefore essential that professionals in the health sector have some mental health knowledge and skills. To meet this need, NIMH trains medical students in behavioral science and interviewing techniques, and seeks to improve their mental health knowledge and skills. Our programs teach primary health care residents to identify, prevent, evaluate, treat, and appropriately refer mental health problems. Training programs prepare psychiatrists to provide consultation and liaison services to primary care training programs and practitioners. Programs are also funded for the education of general and public health nurses. These efforts are identified for a $2.4 million increase in 1980.

Question: How is this integrated with the role of mental health specialists?

Answer: The key issues are identification and referral. A large proportion of individuals who require specialized mental health treatment may never be seen by a specialist because the mental health aspects of their problem are not recognized at the primary care level. Such persons may continue to be treated - often unsuccessfully - in a general health care setting. As primary care practitioners improve their diagnostic skills, it is likely that the number of referrals to mental health specialists will increase. At the same time, the primary care practitioners will be better qualified to treat the less serious mental health problems without the need for referral.

NEW SERVICE PROGRAM

Question: Please explain the "New Services Program" proposed under mental health community programs.

Answer: The Administration will soon submit to Congress a proposed new Community Mental Health Systems Act, based upon the studies and recommendations of the President's Commission on Mental Health, and our past experience with the present community programs. The Act will propose means for Federal leadership in developing and strengthening Federal-State and local partnership in planning and implementing mental health services. It will offer a more flexible approach to assisting communities in developing mental health services that are responsive to the particular needs and capacities of each community. The proposal will give priority to meeting the needs of the underserved and unserved geographic areas and special groups such as the aged, severely mentally ill children and youth, and those with alcohol and addiction problems.

Question: Do you feel that pursuing this new initiative is more important than providing new starts for Community Mental Health Centers?

Answer: The two programs are complementary rather than competitive. The Administration is proposing a new mental health services act which will permit a more flexible approach to assisting States and communities in developing new mental health services, and respond to the recommendations of the President's Commission on Mental Health for greater and more rapid response to the needs of the underserved. Support of new comprehensive community mental health service programs similar to CMHC's is included and will in fact be continued. Those communities already having plans for such programs will be afforded the opportunity of reassessing their plans in the light of more flexible requirements with more responsiveness to the special needs and priorities of each specific community.

Question: What is the likelihood that legislation for this new services initiative will be enacted in time to obligate all of the $30 million involved in 1979 for this new initiative?

Answer: The timing will be close; however, because we feel that the new services initiative meets a variety of major mental health needs, we are making every effort to establish it at the earliest possible date.

Question: How long will the Agency wait for the legislation to pass before using the money to fund new CMHCs?

Answer: We would start to process the necessary paperwork on May 1, and after June 30, we would spend the money for new Operations grants under the existing CMHC legislation. To ensure that all of the funds would be spent for quality projects, we are continuing to receive and review applications for grants under the current legislation. We have also developed various alternatives for allocating the funds to our Regional Offices. Our allocation plan would be in accordance with the present law, but would give priority to those projects which address the underserved areas and population groups covered by the proposed new services initiative.

MENTAL HEALTH PLANNING

Question: Has legislation been proposed or planned to be introduced into this Congress to facilitate the development of improved mental health planning?

Answer: Later on this session of Congress, the Administration will introduce its Community Mental Health Systems Act. This Act, developed by the Department, is in response to a number of the recommendations of the President's Commission on Mental Health including those to improve the mental health planning process and coordinate it with the health planning process. It will address State mental health planning and consolidate state mental health plans previously required under Section 237 of the CMHC Act and Section 314(d) and (a) of the PHS Act. Guidance will be provided so that this new state mental health plan can reflect the new emphasis on unserved or underserved groups. In developing the mental health plans, the state Governor will select the primary locus of mental health planning within the state in a manner that will facilitate the integration of mental health planning and other health planning, such as that carried out under Title XV of the PHS Act, as amended.

Question: Would your agency require additional funds to enact such legislation?

Answer: Part B of the proposed Community Mental Health Systems Act is for State Mental Health System Improvement. Under Part B, funds would be authorized for improving the management and data collection abilities of State Mental Health Programs. At this time, however, we are not requesting funds for these activities.

UNDERSERVED POPULATIONS AND GEOGRAPHIC AREAS

Question: What are some of the major underserved populations and geographic areas in the field of mental health treatment?

Answer: The major underserved populations and geographic areas are those of the chronically mentally ill, children and youth and the aged with mental and emotional disorders, racial and ethnic minorities, those in poverty and persons in the more rural areas. Often, these factors are present in combination. For example, those racial and ethnic minority groups in rural areas, and the children and youth in rural or urban poverty areas are particularly underserved.

Question: How does NIMH intend to give special attention to underserved populations and geographic areas?

Answer: NIMH has been directing specific attention to those groups and areas identified as critically underserved both within the context of general support programs and through specifically targeted, although limited, resources available. For example, under the existing Community Mental Health Centers Program communities are required to identify such high priority special need groups and to plan toward assurance of services to meet their needs. In addition poverty status, extent of underservice, and the presence of such special need groups are basic factors in determining payment priorities. Another example is the two year pilot Community Support Service Program which has successfully developed techniques and program for assisting States and communities to more appropriately serve the chronically mentally ill that are already having impact in 19 States. The proposed new Community Mental Health System Act will afford a range of additional means for giving priority to the underserved. It will include a major effort to assist all States to improve service for the chronically mentally ill, based on the pilot program, major specific focus on improving the Nation's programs of services for seriously mentally ill children and youth, special assistance to communities in the initiation of services tailored to meet the needs of such special groups, and expansion of our program of assistance to States in planning for the manpower needs of the State and its communities including the manpower needed to serve such special needs.

RESEARCH POSITIONS

Questions: I note that you are requesting 137 new positions for extramural research grants. Of this 103 -- or 75% -- are for new grants where a funding increase of $7 million is proposed. Even with the funding increase, why do you need so many additional positions in the "new" category?

Answer: The number 137 appears on page 20 of our Congressional justification and refers to the number of additional grant awards proposed for 1980 - including an increase of 103 new grants. Our positions increases appear under the Program Support activity on pages 39 - 41 of the justification. We are requesting only 11 additional positions for extramural research. These positions are requested in order to keep up with the additional extramural research workload, and to improve the quality of grant monitoring and technical assistance activities.

Question: Why are you projecting a $4 million drop in competing grants -- along with a 49 position decrease in staff?

Answer: As indicated earlier, the 49 refers to the number of grants rather than positions. The NIMH expects to award 49 fewer competing renewal grants in 1980.

CONTRACT WITH GEORGETOWN UNIVERSITY MEDICAL SCHOOL

Question: What level of savings is expected as a result of the contract with Georgetown University Medical School to take over responsibility for the physical health care of patients at the Hospital?

Answer: Ultimately, we expect the savings to be as high as $2 million per year; however, we do not expect to fully attain this level in 1980. These savings will come from two principal sources: direct benefits, as the result of not having to staff and operate an in-house medical and surgical facility; and anticipated savings in the contract cost, resulting from third-party insurance payments made to Georgetown Hospital on behalf of the Saint Elizabeths' patients.

DRUG ABUSE RESEARCH

Question: What percentage of its research grant applications does NIDA expect to fund in FY 1980?

Answer: The National Institute on Drug Abuse expects to receive approximately 579 applications for regular research grants and research scientist development awards in FY 1980. This estimate is based upon having $13,236,000 available for new and competing awards in the budget year. Of the applications received, it is estimated that approximately 55 percent will receive approval by the National Drug Abuse Advisory Council. Of these approved awards, the funds requested would be sufficient to fund approximately 59 percent. Therefore, of all awards received, approximately 33 percent will be funded in FY 1980.

Question: In drug abuse research, you are requesting more dollars and fewer positions. How can you explain this?

Answer: The positions associated with the research activity relate only to intramural research for which the budget request is slightly lower in FY 1980 than in FY 1979. Additional positions associated with the increase requested for extramural programs are requested in the program support activity.

CENTRAL OFFICE STAFF INCREASE

Question: Why are you requesting a position increase of 10 in the central office staff for drug abuse?

Answer: Since FY 1978, the extramural research program has grown steadily from 359 projects and $31,138,000 to a requested level of 491 projects and $46,833,000 for FY 1980. This substantial program increase requires additional staff. Therefore, five positions are requested to help cope with the additional workload generated by these program increases. Also, in recent months, NIDA has taken positive steps toward the improvement of the review and management of the grants and contracts program. In furtherance of these efforts, three positions will strengthen the newly formed Office of Extramural Project Review and two will be to maintain an improved level of quality in contract management.

DRUG ABUSE PREVENTION

Question: What is the current level of support of prevention and intervention activities?

Answer: Within the research activity, NIDA plans to spend $720,000 in FY 1979 and $3,063,000 in FY 1980. In the Community Programs activity, $5,090,000 is budgeted for FY 1979 and $4,705,000 for FY 1980. This is in addition to formula grant funding.

Question: What percentage of total formula grant money is being spent on prevention?

Answer: Our most recent survey information indicates that approximately 30 percent of the formula grant funding is being expended for prevention and education activities within the States.

Question: Do you think you are putting enough emphasis on this aspect?

Answer: We believe the overall increase of about $2 million or 34 percent for prevention activities in 1980 to be appropriate.

Question: Thus far, what approach to prevention seems to be most effective?

Answer: The most effective approach to drug abuse prevention appears to be through prevention programs using the newer prevention strategies such as values clarification courses, classes in decision making, life skills curricula, and peer tutoring. A review conducted by the Prevention Branch indicated that 70 percent of the prevention programs using these strategies showed positive effects on one or more drug specific measures; for example, self-reported drug use, institutional records of drug use, intention to use drugs in the future, attitudes towards drugs, drug knowledge, and academic grades or school attendance. Only 29 percent of these programs showed some negative outcome, for example, increased intention to use drugs in the future. For programs using a drug information strategy, only 46 percent showed positive effects while 46 percent showed negative effects, and 8 percent showed no change.

Question: Last year, Dr. DuPont mentioned that NIDA would like to see more work at the State and local level on prevention aspects and a greater coordination between the State drug abuse agencies and their departments of education. What has happened along these lines during the past year?

Answer: Consistent with this objective, significant progress has been made during the past year. Specifically, a prevention coordinator position has been established in 31 States. The primary function of this position is to coordinate activities with State and local agencies that have objectives in drug prevention, youth development, or health promotion. A training workshop was sponsored by NIDA in February 1979 to further coordination and to develop plans to expand the program to all interested States.

Question: What is the major emphasis of the prevention education activities of the Institute?

Answer: NIDA's major prevention emphasis is twofold. First, is the acquisition of new knowledge through research and/or evaluation. Second, is technology transfer which includes the establishment of prevention coordinators within States to assist in the development of new prevention knowledge and the dissemination of this information to other local governmental units.

EVALUATION OF DRUG ABUSE EDUCATION AND PREVENTION

Question: Have you ever done an evaluation of your education programs in drug abuse?

Answer: The DHEW Office of Education has primary responsibility for the development of effective educational programs in drug abuse. However, NIDA has supported public education programs in drug abuse

prevention through the use of national media campaigns. In FY 1978, NIDA specifically allocated $173,000 to evaluate the National Drug Abuse Prevention Campaign for the first year cost of a two year effort. Preliminary results from market test sites indicate that campaign messages were heard, understood, and retained by a larger audience than for most public service spots. The second year effort will attempt to identify specific impact results.

Question: How much has been spent on the evaluation of the Institute's prevention activities, and what are the results?

Answer: In FY 1978, NIDA spent $2,120,000 in grants to evaluate model approaches to the prevention of drug abuse through education, intervention, information, and alternatives projects. Grants are awarded to those applicants who can demonstrate a thorough knowledge of the field of drug abuse prevention and who have the capacity to comprehensively evaluate the long-term impact of their projects on youth drug taking behavior and youth attitudes toward drugs.

Preliminary evaluative research findings suggest that drug abuse prevention programs can change youth attitudes toward drug taking and reduce their drug taking behavior. For example, an evaluation of the Gloucester Drug Prevention Program (a NIDA grant) in Gloucester, Massachusetts, found that youth participating in this program developed more positive attitudes of themselves and their communities, and reduced their use of drugs. In addition, an evaluation of the Ombudsman Drug Prevention Program (a NIDA grant in Charlotte, North Carolina) indicated that fifth and sixth graders participating in the program tended to reduce or stop their use of a variety of licit (e.g., cigarettes) and illicit drugs (e.g., marihuana).

In addition, NIDA is spending $500,000 (FY 1978-1980) for the design of a National Prevention Evaluation Resource Network (NPERN) that will enhance the capacity of States and local programs to assess the effectiveness of their prevention efforts. This design contract has been awarded to the States (Single State Agency for Drug Abuse) of Wisconsin, Pennsylvania, and New Jersey, and will be completed in February 1980.

DRUG ABUSE THIRD-PARTY PAYMENTS

Question: Last year you told the committee that NIDA and Blue Cross were jointly studying the feasibility of broad-based, outpatient benefits to cover drug abuse treatment. Has the study been completed? If so, what were the conclusions?

Answer: In January 1978, NIDA contracted with the Blue Cross Association to conduct a one year preliminary study of the feasibility and desirability of offering a drug dependence treatment benefit nationwide through the Blue Cross organization. This study was completed and negotiations are now in process to launch a second phase demonstration to field test the benefit package in two select Blue Cross Plans. This is envisioned as a three year effort.

Under the contract study, a survey of the 68 Blue Cross Plans documented and reinforced earlier information regarding the lack

of availability of drug dependence treatment coverage. Although 87 percent of the responding Plans cover detoxification treatment at general hospitals under their basic contract, less than half of the Plans (43 percent) pay for any rehabilitative treatment. Only 17 percent of responding Plans cover inpatient rehabilitative treatment at free-standing treatment centers under their basic contract and, on an outpatient basis, only 3 percent of responding Plans cover rehabilitative therapy at these sites. The results of the survey indicate that, in many Plans, the available coverage of drug dependence treatment is inadequate. Further, where coverage is available, it usually excludes the most common and inexpensive treatment at free-standing centers.

In addition to conducting the Plan survey, Blue Cross Association also developed a model benefit for drug dependence treatment. The critical considerations in the design of this health care benefit were its clinical adequacy, marketability, and administrative feasibility. Based on extensive study and the input of a national advisory committee composed of drug treatment providers, Federal and State Government officials, representatives of labor and industry, and representatives of several Blue Cross Plans, the Association is now prepared to recommend a benefit which would cover up to $5,000 of care in an appropriate mix of inpatient, residential, or outpatient settings. An additional, nonrenewable lifetime reserve of $1,000 may also be used for outpatient care after two 12-month ($5,000) benefit periods are exhausted.

Because the marketing of a drug dependence treatment benefit is unprecedented, little directly applicable data were available to guide its development. Thus, although the first year study generally supported both the feasibility and desirability of offering the benefit, the results were not unequivocal. Four areas will receive special focus during the demonstration phase. They are benefit design; marketability, to determine if decisionmakers will purchase a drug dependence treatment benefit for group accounts; utilization, to determine whether the benefit will be utilized; and treatment provider contracts between Plans and drug programs.

ARGUMENTS AGAINST THIRD PARTY REIMBURSEMENTS

Question: What are the principal arguments of third party payors against the inclusion of drug treatment in the range of services they will cover?

Answer: Historically, the drug abuse treatment system has operated outside the mainstream of health care delivery and financing. Although private health insurance has served as a primary method of financing care in the general health delivery system, meaningful interaction between the health insurance section and the drug abuse treatment system has just emerged in the last two years. Traditional arguments against inclusion of drug abuse treatment in private health insurance have included: controversy over classification of drug abuse as a disease; insurers taking the stand that addiction or dependency was a self-inflicted injury and, therefore, noncompensable; treatment being rendered by providers whose professional status was deemed questionable by insurers; treatment settings not conforming to the "medical model," i.e., neither a hospital nor a physician's office; the questioning by insurers of the efficacy of

treatment and the prospects of a "cure"; the recidivism rate among drug abusers which alienated insurers who presumed uncontrollable costs for repeated episodes; and the fact that market demand for drug abuse insurance benefits has been weak.

At the present time, however, there are indications of a more favorable future for reimbursement from private insurers for drug abuse treatment. This outlook is based on a number of factors: the extensive drug abuse treatment network has matured as a health delivery system - standards have been developed and are being implemented to assure quality services; large groups of employed persons, particularly unions, have recognized the need for substance abuse coverage and have negotiated for its inclusion in their health insurance policies; and a number of States have passed legislation which mandates alcohol and drug treatment benefits in group health insurance.

While some policy restrictions are being lifted as terms of coverage are broadened, we do not envision a significant impact on NIDA programs. It is well documented that most private health insurance is held by employed populations, and less than 30 percent of the clients admitted to NIDA programs are employed. Indeed, only 34 percent of our clients are covered by some form of health insurance, and approximately 16 percent hold private insurance. However, even where there is such eligibility, the extent of specific coverage for drug abuse treatment in free-standing centers is not known.

Question: Are the Single State Agencies much involved in the effort to develop third party revenue sources?

Answer: Single State Agencies (SSAs) are very much involved in efforts to generate third party revenues. These monies are needed not only to meet local matching requirements for NIDA-supported programs but also to assist in the funding of the many programs which rely on a variety of non-Federal financial resources.

Question: Do they have much incentive to do this?

Answer: Yes, third party reimbursements enable the States to complement SSA appropriations and thereby to extend their impact for expanding treatment services. States which have been most successful in capturing third party dollars have developed strong interagency relationships with key State reimbursement agencies.

Also, for example, Pennsylvania undertakes a variety of activities to assist community programs in qualifying for reimbursement. The SSA is developing an interim licensing procedure to facilitate recognition by Blue Cross agencies and is using funds where needed to meet the costs for approval by the Joint Commission on Accreditation of Hospitals (JCAH). In addition, the State, through its County Authorities, is easing the cash flow problems of community programs by allowing them to bill and be paid by the county in advance of actual reimbursement from third party agencies.

DRUG ABUSE GRANTS AND CONTRACTS MANAGEMENT

Question: How many times, during 1978, did you withhold payment to contractors who failed to make deliveries as stipulated?

Answer: During fiscal year 1978 there was only one occasion when NIDA found it necessary to withhold payment to a contractor for failing to make delivery as stipulated.

Question: How many times did you withhold payment or withhold continuation approval on grants or contracts because of delinquency in the reports you require?

Answer: The situation did not arise in the contracts area. However, during fiscal year 1978, seventeen grant awards were delayed because of delinquent reports. Three other grant awards were delayed due to programmatic and clarification concerns.

Question: Have any of your projects or contract approvals been investigated by the Inspector General during the past year?

Answer: In the contracts area, during calendar year 1978, the Inspector General investigated three procurements. Two of these had been awarded and were investigated for possible conflict of interest. The Inspector General found no conflict of interest. A third procurement, which was never awarded due to programmatic and procurement deficiencies, was also reviewed by the Inspector General. This review was concerned with program need and contracting out versus in-house effort. The Inspector General recommended that an independent review group be established to review this program, specifically regarding the above items. This review group determined that there was a definite need for the program and that it could not be accomplished with the present in-house NIDA staff.

In the grants area, during calendar year 1978, the Inspector General reviewed approximately 10 projects that were mentioned in the newspaper column written by the staff of Jack Anderson. There were no significant management problems or deficiencies in the NIDA grants management process uncovered by the Inspector General.

REGULATIONS FOR SECTIONS 409 AND 410, DAOT ACT

Question: What happened to the regulations you have been preparing on Section 409 and 410 grants and contracts for a number of years now?

Answer: Regulations establishing Part 54b of Title 42 Code of Federal Regulations, which sets forth the formula for alloting grant funds appropriated under Section 409 of the Drug Abuse Office and Treatment Act, were initially published in February 1973, amended in April 1974, and further revised in June 1976. The balance of implementing regulations for Section 409 was published as a Notice of Proposed Rulemaking in August 1973, revised to accommodate public comments received and to reflect legislative amendments to the Act enacted by P.L. 94-237 and P.L. 94-371, and republished as a proposal in January 1977. Section 410 of the Act (authorizing drug abuse project grants and contracts) permits but does not require the promulgation of implementing regulations.

Question: What is holding them up?

Answer: The processing of final 409 regulations, which incorporate additional changes made to reflect legislative amendments to the

Act enacted by P.L. 95-83 and P.L. 95-461, are now being completed in the Office of the Secretary. If the Department determines that Section 410 implementing regulations are necessary, such regulations will be proposed and promulgated separately.

STATE PLANNING GUIDELINES

Question: Last year you told us you were assigning a high priority to completing the issuance of State planning guidelines for formula grants. Are the guidelines now in effect? Give us a brief description.

Answer: Yes, new guidelines for State plans were published in early March 1979. The format is intended to enable States to prepare a succinct, well organized planning document.

The guidelines call for a plan format which sets forth: (1) A State's philosophy or policy on Drug Abuse Prevention, (2) A statement of need with an analysis of the statewide indicator studies on drug usage, and (3) A set of eight miniplans for program functional areas which contain performance reports for the previous year's work, goals and objectives for the coming year, and an implementation strategy and cost analysis for each objective.

The eight program functional areas are:

Administration - Describing the structure and oversight functions of the SSA.

Planning and Coordination - Addresses the interface with Alcohol, Mental Health, and all human support systems such as Vocational Rehabilitation.

Treatment and Rehabilitation - A complete analysis of all treatment in the State, listing capacities by modality and environment.

Management Information Systems - A description of how the management information systems supports SSA function.

Research and Evaluation - The States carry out a very limited program of research with its 409 funds. Under the guidelines, the States present a summary of the research efforts which they intend to support for the coming year. Evaluation deals with the monitoring devices used by the SSA to ensure quality.

Prevention - A description of the statewide prevention programs including public information, education, alternatives, and intervention.

Training - The State's effort to train adequate personnel in all aspects of drug abuse programming.

Criminal Justice Interface - Describes the State's efforts to develop liaison with the enforcement, judicial, and corrections systems.

SITE VISITS FOR MONITORING DRUG ABUSE PROGRAMS

Question: During 1978, how many site visits were paid to grant or contract recipients for monitoring purposes?

Answer: During fiscal year 1978, program offices and divisions made 978 site visits for the purpose of monitoring grant and contract recipients. The grants and contracts management branches made an additional 52 site visits in FY 1978 for monitoring purposes.

Question: How does that compare with the previous year?

Answer: During fiscal year 1977, the comparable number was 981 for program offices and divisions. For the grants and contracts management branches the comparable 1977 number was 47.

UNDERSERVED POPULATIONS AND GEOGRAPHIC AREAS

Question: What are some of the major underserved populations and geographic areas in the field of drug abuse?

Answer: We are currently examining the special treatment needs of American Indians, women, and youth and the adequacy of rural treatment delivery.

Question: How does NIDA intend to give special attention to underserved populations and geographic areas?

Answer: Due to the requirement of State planning, each Single State Agency must do a needs assessment for drug abuse activities on a yearly basis which enables them to equitably distribute treatment slots to various population groups located in different geographical areas.

The Institute continues to take initiative in seeking to ensure that drug abusers in the various affected population groups and geographic regions receive adequate attention. For example, last year without additional funding, we redirected resources to provide funds for 20 programs which emphasize the special treatment needs of women. This year, we have as an Institute objective to fund at least 500 reallocated treatment slots directed for American Indians. NIDA has also conducted a major rural drug abuse study and is working with each of the States to identify their appropriate rural drug abuse treatment and prevention strategies.

In addition, the following language is being inserted in each statewide services grant or contract: "In planning for and delivering treatment services, the Contractor shall make provision for the treatment needs of American Indians, women, youth, Hispanic Americans, Blacks, and Asian Americans."

TASK FORCE ON ALCOHOL ABUSE AND ALCOHOLISM

Question: How does your 1980 budget request compare with the recommendations of last year's task force on alcohol abuse and alcoholism?

Answer: The FY 1980 President's Budget request includes $35.5 million to support the Department's FY 1980 Initiative on Alcoholism and Alcohol Abuse. The $35.5 million supports research, training, prevention and treatment in six areas: $11.8 million for Women's programs, $12.3 million for Youth programs, $3.6 million for Fetal Alcohol Syndrome programs, $5.7 million for Occupational Alcohol programs, $1.4 million for an HEW Employee Assistance program, and $.7 million for Domestic Violence programs. This represents 67 percent of the $52.9 million recommended by the Department's Task Force which included support for research, training, prevention, and treatment in the following areas: $18.3 million for Women's programs, $18.6 million for Youth programs, $6.2 million for Fetal Alcohol Syndrome programs, $6.1 million for Occupational Alcohol programs, $1.4 million for an HEW Employee Assistance program, and $2.3 million for Domestic Violence programs.

ALCOHOL CONSUMPTION DURING PREGNANCY

Question: What efforts has NIAAA made to advise the public of the dangers of alcohol consumption during pregnancy?

Answer: The 1978 fetal alcohol syndrome (FAS) awareness and distribution effort began with the syndicated storyline in the "Apt. 3-G" comic strip. The story which ran for 5 months, January 24 - July 9, concerned a young woman who abused alcohol, became pregnant and wanted to be a mother. "Apt. 3-G" reaches over 12 million readers.

Early in 1978, the National Clearinghouse for Alcohol Information (NCALI) processed a mailing to 77,000 physicians (22,000 obstetricians) of an attractive phamphlet "Alcohol and Your Unborn Baby" with a poster asking them to inform their patients and offering additional copies. An open letter to physicians on FAS in American Medical Association's American Medical News reached physicians who were not included in the OB/GYN family physician list. An overwhelming immediate response of 7,000 followed the mailing.

At the same time, State Alcoholism Authorities, State Prevention Coordinators, State and Territorial Health Officers and City Health Officers received a package to which there was a 78 percent response. Eleven States conducted FAS campaigns in 1978 for which NCALI provided materials.

The 260 Planned Parenthood affiliates and maternal and/or baby and health oriented membership organizations with newsletters were mailed an FAS package encouraging them to include an article in their newsletter. Requests are for sizeable quantities. In all, 3,625,000 copies of "Alcohol and Your Unborn Baby" have been printed and distributed.

Question: How much daily consumption of alcohol is detrimental to the fetus?

Answer: It is extremely difficult at this time to state a specific level of daily alcohol consumption which will or will not be detrimental to the fetus. From the scientific evidence available at this time, it appears that a definite risk is established with consumption above 3 ounces of absolute alcohol a day. (One ounce of absolute alcohol is the equivalent of two 12 ounce cans of beer, two 5 ounce glasses of wine, or two standard mixed drinks.) However, we can not be sure that this constitutes a truly safe level. Because of the severity of the full fetal alcohol syndrome (FAS), it is likely that some partial attributes of FAS are at risk at lower dosages, (e.g., physical abnormalities as well as abnormalities of attention, behavior, and learning).

ALCOHOLISM CLINICAL TRAINING

Question: Mr. Archer, why have you decided to provide no new starts for alcoholism clinical training in 1980?

Answer: Reductions in clinical training should not be construed to mean that these forms of training are no longer necessary. The decision not to award new clinical training grants is based on the general austerity of the Federal budget for 1980, which has caused the Institute to limit funding to prior year commitments in a number of program areas.

It is important to note, however, that the Institute intends to fund new research training awards in 1980. The Institute has a strong commitment to continue the development of high quality alcohol research scientists, and to assure adequate knowledge and sensitivity about alcohol-related problems among a wide range of health and social service caregivers, through its ongoing research and clinical training activities.

STATE ALCOHOLISM SERVICES DEMONSTRATION PROGRAM

Question: I understand that you are implementing a State Alcoholism Services Demonstration Program. Have you selected the States which will be awarded grants under this new program?

Answer: No. The announcement and guidelines for this demonstration grant program have just been completed. Any State may apply for a State Alcoholism Services Demonstration Program (SASDP) grant. All applications will be considered under our dual review system which consists of a technical review by experts in the field of alcoholism and a final review by the National Advisory Council on Alcohol Abuse and Alcoholism.

Question: How much money will be associated with this program in 1979 and 1980?

Answer: Until the final selection of State applicants for this program, the amount of money associated with this program will be unknown.

Our best estimates at this time would have to be based upon the range of grant programs by State. The amount could be as low as $2 million or as high as $14 million, but would probably average about $8 million in both years.

SERVICE REQUIREMENTS FOR CMHC'S

Question: What effect will the recent changes in the basic services requirements of Community Mental Health Centers (CMHC's) have on the availability of alcoholism treatment programs?

Answer: These changes will not have any significant impact on the availability of alcoholism services in new CMHC's since it only extended from two to three years the length of time in which these services must be made available. This will serve to allow the community enough time to develop the most appropriate services. For centers initially funded under the old staffing grant program, there will be no substantial effect on currently provided alcoholism services since the National Institute of Mental Health intends to assure that they will be maintained.

UNDERSERVED POPULATIONS AND GEOGRAPHIC AREAS

Question: What are some of the major underserved populations and geographic areas in the field of alcoholism?

Answer: The Institute has identified a number of population groups which have been designated as underserved in the alcoholism field. They are: racial and ethnic minorities, American Indians and Alaskan Natives, poverty populations, women, youth and the aged. Due to the universal nature of alcoholism and alcohol abuse, projects are funded throughout the nation.

Question: How does NIAAA intend to give special attention to underserved populations and geographic areas?

Answer: There is a special initiative in this budget which the Department has developed to support projects to meet the needs of underserved populations, particularly for women and youth. The Alcohol Initiative supports research, training, prevention, and treatment totalling $11.8 million for Women's programs and $12.3 million for Youth programs.

In addition, as a matter of course, specific staff have been designated as "national lead people" to assist in stimulating the development of services for Blacks, Hispanics, Poverty, Aged, Women, and Youth populations. A special section was created in the Division of Special Treatment and Rehabilitation to help expand services to American Indian and Alaskan Natives. These national leadership staff are engaged in the development of activities to enhance the quality of care and to expand the treatment capacity for these groups on a nationwide basis. Also, the Institute has completed a series of workshops that brought together experts serving Black persons to assist NIAAA in developing future program directions that would be responsive to the needs of this population; a similar workshop effort is being planned for the Hispanic American population.

SUCCESS OF ALCOHOL PROJECTS

Question: To what extent have alcohol treatment projects been successful, in terms of the number of clients served and services provided, after they complete their 8 years of NIAAA funding?

Answer: On the basis of data collected during their operation as NIAAA-funded projects, these programs have proven successful in reaching and helping increased numbers of people. Over 900,000 persons have been provided services in these projects since 1971. Recovery rates have been substantial, ranging from 45 percent in programs serving populations comprised of individuals with long histories of problem drinking, such as public inebriates, to 70 percent in earlier intervention programs, such as occupational and drinking driver projects. Most of the projects originally initiated by NIAAA are continuing to receive support although only 13 percent of 452 have passed 8 years of support.

Question: What progress is NIAAA making in developing program standards for the treatment projects it funds?

Answer: Federal regulations have been promulgated that require each project applicant for a treatment grant shall set forth in its application a performance standard (or standards) to measure, or research protocol to determine the effectiveness of services provided. In addition, the Institute has issued revised guidelines and instructions for alcoholism treatment and rehabilitation services grants that require an evaluation plan to assess the progress made in achieving the project's goals and objectives. Staff of the Institute are actively engaged in further refinement of the National Alcoholism Program Information System (NAPIS) to assure its maximum utility as an evaluative mechanism to assist individual projects in increasing their level of performance. NIAAA is also engaged in a series of evaluative/research activities that are or will be developing specific classification and evaluation criteria that are expected to further increase the performance level of its treatment and occupational programs.

ALCOHOLISM PREVENTION EDUCATION

Question: What is the major emphasis of the alcoholism prevention education activities of the Institute?

Answer: Our prevention message emphasizes the decisionmaking involved in the use of alcohol. Informed decisionmaking entails using full and factual information to make thoughtful choices about whether, when, and how to use beverage alcohol. Implicit in the concept of informed decisionmaking is the fact that a sizeable number of people choose not to use alcoholic beverages. Our policies and publications encourage those who do not drink to respect that decision, and we urge those who do drink to be informed about the risks and problems associated with the use of alcohol.

Question: How much has been spent on the evaluation of the Institute's education activities and what are the results?

Answer: The Institute funded a contract for $170,000 in 1976 to evaluate the effectiveness of the Prevention Demonstration Grants.

In addition, an instrument was developed by the contractor to assist NIAAA in measuring the progress and effectiveness of the projects while they are being funded. The instrument provides information needed to improve program content and management efficiency. In FY 1978, approximately 10 percent, $300,000, of the funds awarded to grantees to test prevention strategies is expended on process and outcome evaluation. Analysis of the outcome of prevention programs funded by NIAAA has generally shown the projects to be successful in accomplishing intermediate goals such as increasing knowledge about alcohol, modifying attitudes and values or increasing decisionmaking and coping skills.

Question: Have you ever done an evaluation of your education programs in alcoholism? Every year, we keep putting more and more emphasis on teenage and women's alcoholism. Every year we are told it is getting worse and worse.

Answer: As I previously mentioned, the Institute funded an evaluation contract in 1976 and has funded several longitudinal studies to measure self-reported behavior change. Also, based on the demonstration nature of prevention education programs, each grantee must conduct a process and outcome evaluation of the strategies being tested under the grant.

The Department's FY 1980 Initiative on Alcoholism and Alcohol Abuse has singled out for particular attention two specific segements of the population, women and youth, among whom the incidence of alcoholism is increasing at alarming rates and to whom few efforts historically have been directed.

The Department's Initiative includes funds for a contract specifically designed to evaluate a proposed nationwide multimedia campaign focusing on the alcohol problems of women and youth as well as an overall assessment of a proposed pilot program to reduce alcohol-related traffic accidents among youth.

ADAMHA PREVENTION

Question: What portion of your agency's budget is a component of the Secretary's new prevention initiative?

Answer: Of the total budget request of $916,510,000 now before the Congress, $13,900,000 is associated with the Secretary's prevention initiative. In addition, the $99,100,000 mental health services initiative to be transmitted later as a legislative package includes an additional $6,000,000.

Question: How much of this amount is "new money" in 1980 and how much was included in the 1979 base and is merely associated with this initiative?

Answer: All of the $6,000,000 included in the mental health services initiative is "new money." Of the $13,900,000 now requested, $1,100,000 was in the 1979 base. This $1,100,000 is budgeted in the alcohol community program activity. Taken

as a whole, including the amount included in the legislative package to be transmitted later, $18,800,000 of the $19,900,000 is "new money."

FORMAL WORKING RELATIONSHIP WITH NIH

Question: Has a formal agreement been finalized setting forth principles to guide the coordination of NIH and ADAMHA research programs? What are the provisions of this agreement?

Answer: On March 5, 1979 the Administrator of ADAMHA and the Director of NIH signed an agreement setting forth principles and operating procedures to guide the two agencies in continuing and further establishing relationships and operational plans to coordinate their respective research programs and to avoid unnecessary duplication of research efforts. The agreement covers six major areas of coordination as follows:

1. Policy Development and Planning: The two agencies will continue meeting to address specific policy and planning issues, to coordinate programs, to develop and propose to the Secretary legislation as it affects their mutual responsibilities, and to confer in the development of regulations.

2. Research Manpower Development: Monthly meetings will ensure coordination of the administration and management of research training activities, including determining national requirements for biomedical and behavioral research personnel.

3. Research Program Development: The two agencies will continue joint funding of projects of mutual interest.

4. Information Coordination and Development: Based upon ADAMHA information, NIH will continue to provide computer, analytical, and reporting services to assist ADAMHA in the referral and review of applications and awarding of grants.

5. Operational Coordination - Research Grants and Contracts: NIH will continue to receive, process, and assign research grant applications sent to the Public Health Service, including the making of dual assignments to the two agencies where appropriate.

6. Operational Coordination - Intramural Research: NIH and ADAMHA scientists will continue to collaborate in a wide variety of research projects, facilitated by the location of the NIMH intramural program on the NIH campus and the anticipated location of the clinical portion of the NIAAA intramural program in 1981.

The agreement is to remain in effect until amended by mutual consent.

PROGRAM MANAGEMENT

Question: You have requested an increase of 26 positions for program management activities. What portion of these positions are to be used to improve grants and contracts monitoring? What portion will be used to improve civil rights activities?

Answer: Included in the 26 new positions for the Office of the Administrator are 4 positions to improve the management of grants and contracts program. These positions will address the Departmental initiative for increased involvement in monitoring the quality of pre- and post- award cost and price analysis and assuring appropriate corrective action on deficiencies cited intended in internal and external audit reports.

The Department's initiative in civil rights involves the transfer of major civil rights responsibilities to the operating agencies. The 1980 budget includes 1 position to meet the additional tasks.

Question: What is the "Operation Common Sense" initiative that you mention in your justification under program management?

Answer: In response to the President's Executive Order 12044 the Secretary implemented "Operation Common Sense" commiting the Department to the issuance of clear, simple, and concise regulations in a timely manner. This initiative will require that we speed up the drafting of regulations, insure that new rules are short, clear and simple and that existing rules are rewritten where necessary to produce more helpful and less confusing regulations. It also requires that we reach out more aggressively for effective public participation, including timely involvement by those specialized constituents affected directly by the Department's rulemaking.

MINORITY NEEDS

Question: The committee would appreciate learning of your Administration's plans for insuring that our nation's minorities are adequately served, especially in the delivery of mental health services, the development of an adequate mental health manpower pool of minority professionals, and in the funding of projects that specifically address minority mental health problems. As you are aware, Senator Inouye has proposed establishing an identifiable unit within your Administration that would specifically address these issues. Do you personally feel that such legislation is necessary at this time, or have you administratively addressed the underlying issues satisfactorily?

Answer: ADAMHA utilizes several mechanisms to respond to the needs and concerns of minorities. These are: (1) specific activities and programs targeted toward minority groups; (2) the involvement of minority persons in the review of grants; and (3) the use of minority persons as consultants and advisors in program and policy areas of which the most obvious example is the Minority Advisory Committee (MAC).

The ADAMHA Minority Advisory Committee advises the Secretary and the Administrator, ADAMHA, on policy, programs and activities regarding minority alcohol, drug abuse, and mental health matters, and makes recommendations for possible solutions to meet the needs and concerns of minority groups throughout the United States. Each of the Institutes also has special efforts in this area:

°The Center for Minority Group Mental Health Programs, established within NIMH in November 1970, serves as a focal point for Institute activities which bear directly on improving the mental health of minority groups and on increasing the number and competence of minority persons engaged in mental health research, training, and services. The Center also sponsors conferences which bring together for discussion and information exchange professionals and leaders in mental health concerned with minority mental health issues and problems. As a result of the Minority Center's leadership and efforts, six research and development Centers have been established by NIMH to design, conduct and implement research programs relevant to minority groups.

°In an effort to be responsive to minorities, NIAAA has placed emphasis on providing funding support to these target populations. The Institute's philosophy and operational policy in the treatment area is to assist minority groups to share responsibility for planning and initiating appropriate programs. Though its Indian, Black, and Spanish Alcoholism programs, NIAAA assists local communities to provide outreach, referral, advocacy, counseling and information services to minority persons who are affected either directly or indirectly by alcoholism.

°NIDA, through its community assistance programs, provides financial and technical assistance for treatment and rehabilitation services to local communities. The financial assistance is provided though State agencies and local community action groups. A portion of this assistance is used for the identification, treatment, and rehabilitation of minority drug abusers and minority drug dependent persons. Minority groups are also represented in the agency's review process for research and training grants, both at the peer level in the Initial Review Groups as well as in the final review by the National Advisory Councils for Alcohol, Drug Abuse, and Mental Health.

We are not convinced that Senator Inouye's bill to provide for the establishment of a Division of Minority Mental Health Programs would improve efforts to provide services to minority persons. As indicated, each of the Institutes is already engaged in a significant level of activities related to minorities.

Rather than a Division in NIMH, we would favor strengthened coordination through a unit within the Office of the Administrator which would focus soley on minority issues and concerns. Such a unit would have generally the following functional responsibilities:

° Analyze agency policies and procedures to insure that the needs of minority groups are adequately addressed;

° Develop basic strategy for ADAMHA to follow relative to increasing the effective impact of the agency's programs on minority groups;

° Develop and implement tracking systems for monitoring Institutes' programs and the attainment of Minority Affairs objectives;

° Facilitate joint funding and projects between Institutes, Office and Divisions;

° Advocate for minority concerns;

° Continue to provide staff and executive level support furnished to the Minority Advisory Committee up until now by the Office of Program Coordination within the Office of the Administrator.

The unit would carry out a policy development and coordination role. Its direct relationship to the Administrator would permit the establishment of program and funding goals across the Institutes and the opportunity to monitor the implementation of these goals.

PSYCHIATRIC NURSES

Question: The committee would also appreciate learning of your personal views as to whether your administration truly believes that our nation's psychiatric nurses are bonafide professionals? This issue is being raised because there have been numerous allegations that there is a systematic exclusion of psychiatric nurses from your various decision-making and policy-recommending internal bodies. Accordingly, the committee would appreciate receiving a detailed report from you as to the percentage of psychiatric nurses that are, in fact, on your task forces, etc.

Answer: We are committed to the concept of psychiatric nurses as bonafide professionals within our Nation's health and mental health care system. We have demonstrated this concept in a variety of ways. Psychiatric nurses have and will continue to be given serious consideration for current vacancies on the National Advisory Mental Health Council, which is the highest review authority for grant applications in the area of mental health. We intend to nominate a psychiatric nurse for one of these vacancies.

There are seven psychiatric nurses in senior, policy level positions on the NIMH staff. The NIMH maintains a Psychiatric Nursing Education Branch, staffed exclusively by nurses and providing annual support for national training needs. This Branch receives advice and guidance through its Psychiatric Nursing Education Review Committee. This committee consists of nurses, and was recently determined by the Secretary to be essential and was excluded from the overall redirection in the number of advisory committees maintained by the Federal Government. In addition, at least two other chartered initial review groups receive applications relevant to psychiatric nursing, and require and have such expertise among their appointed membership. When we were recruiting for the NIMH Director's position, nursing candidates were sought and given every consideration.

No actual data are available on the number of psychiatric nurses who are, in fact, serving on our numerous task forces and committees. Collecting this data is difficult since nurses in these groups very often have moved into positions of broader responsibility in science or administration where they function as science administrators, deputy directors, and program consultants.

SINGLE FACILITY CONCEPT

Question: Is ADAMHA continually monitoring the projects funded to determine where drug abuse, alcoholism and mental health services should be coordinated and integrated?

Answer: The Agency is actively seeking and promoting opportunities to improve coordination among the three programs and with other elements of the human services system, but there are limitations to the integration of alcohol, drug abuse, and mental health services imposed by the separate legislative authorities as well as the authority given ADAMHA.

However, Federal guidelines for the development of State alcohol, drug abuse, and mental health plans require that coordination in plan development takes place at the State level. In line with this requirement, ADAMHA has recently developed and distributed combined State plan guidelines which will facilitate the submission of a single State plan for alcohol, drug abuse, and mental health. To date, four States have submitted an approved combined State ADM plan. For fiscal year 1979 nine States are expected to submit such plans. In addition, ADAMHA is testing the feasibility and effectiveness of combined site visits involving staff from the regional office, the Institutes, and the States. ADAMHA and Region IV are evaluating a combined site visit to a community mental health center in North Carolina. Combined site visits provide those grantees interested in coordinating and integrating ADM services an opportunity to receive consultation and technical assistance. If the evaluation indicates that combined site visits are beneficial to grantees, they will be extended to other regions.

MENTAL HEALTH PROFESSIONALS

The subcommittee requested and received the following additional information from Dr. Herbert Pardes, Director of the National Institute of Mental Health,on the supply of, and demand for, mental health professionals:

Following the recent 1980 appropriations hearings for Alcohol, Drug Abuse, and Mental Health, you requested some additional information on the projected supply and demand for mental health professionals. The request originated from our testimony on the 1980 training budget proposals relating to Mental Health. The requested information is enclosed.

During the hearings, I testified that one recent survey of mental health professional needs indicated that some 3,200 positions were presently open. As the enclosed information will indicate, this number represents only one portion of our total unmet needs. The survey covered only those positions known to the State mental health authorities, and did not address the needs of the local, nonprofit, or private sectors -all of which play a role in the delivery of services to underserved areas and population groups. Even the 3,200 positions reported must be regarded as a conservative estimate, since the number reflects the scaled down expectations of State mental health programs which would not commit vacant positions to professional fields in which there is presently little realistic prospect for recruitment.

Recognizing the limitations just stated, the enclosed report derives unmet mental health professional needs from a combination of three factors: total numbers available; capacity of the existing educational system to replace losses; and percentage of the total population estimated both to require and utilize mental health services. Despite the many variables involved, we find that our latest estimate of requirements has remained quite consistent with similar estimates developed in prior years.

SUPPLY AND DEMAND FOR MENTAL HEALTH PROFESSIONALS

It is estimated that in 1980, as well as the forseeable future, there will continue to be a shortage of psychiatrists, psychologists, psychiatric social workers, and psychiatric nurses. There are approximately 193,000 other mental health professional and paraprofessional workers currently employed in mental health facilities. It is difficult to assess future supply and demand for these latter groups, due to the varied nature of their training and employment.

The following table sets forth the most recent available data (1975) on the current supply of core discipline professionals. Supply and demand are then projected for 1980 and 1985. The 1975 data assumes a 2.5 percent utilization rate by the national population. The rate is derived from studies of the number of patients seen, as well as treatment episodes in mental health facilities. It includes only that portion of the population with serious mental illness requiring specialized professional care, and is limited by the number of mental health professionals available. It is also impacted by the degree to which primary health care providers may not recognize mental health problems, and therefore not refer some patients to treatment in a mental health setting.

Data on Availability and Demand

	Psychiatrists	Psychologists	Psychiatric Social Workers	Psychiatric Nurses
I. 1975 Data - 2.5% Utilization:				
Available supply..	26,500	21,000	21,000	38,000
II. 1980 Projection - Assuming 3.5% Utilization:				
A. Est. Demand...	38,900	30,800	30,800	46,900
B. Est. Supply...	28,800	24,200	26,400	43,500
C. Est. Shortfall	10,100	6,600	4,400	3,400
III. 1985 Projection - Assuming 3.5% Utilization:				
A. Est. Demand...	40,900	32,300	32,300	48,400
B. Est. Supply...	30,000	28,500	30,400	47,600
C. Est. Shortfall	10,900	3,800	1,900	800

The 1980 and 1985 data assume a 3.5 percent utilization rate. This is a conservative projection, in view of a continued rise in the utilization of psychiatric services and the prevalence of mental disorders in the population. It assumes some expansion in the number of community mental health centers, and is applied against Census Bureau Series "E" estimates, which assume low population growth to 224 million in 1980 and 236 million in 1985. In fact, a more realistic estimate would point to a 3.75 -4.00 percent utilization rate.

The supply estimates project current production rates, adjusted for minimal rates of attrition from the existing manpower pool. Production has dropped sharply for psychiatrists, because of limitations placed on the number of foreign medical graduates entering the country or undertaking psychiatric residency training. The numbers also reflect declines in the number of U.S. medical graduates entering psychiatric residency. Estimates of the number of available psychiatrists includes the number of residents in training, as well as those in actual practice. The numbers of available psychiatrists are somewhat lower than previously reported estimates, due to the availability of more recent source data.

The data for psychiatric nurses reflects some shift in employment from inpatient mental health facilities to health maintenance organizations, emergency facilities, community mental health centers, and nursing homes providing care for the aged who are mentally ill. The increase in demand for psychiatric nurses is not as great as in other professions because nurses are predominantly employed by inpatient facilities, whereas new demand is mainly for outpatient personnel.

Conclusions

If the nation is to maintain the same ratio of professionals to clients as existed in 1975, we will - in 1980 - require an additional 10,100 psychiatrists, 6,600 psychologists, 4,400 psychiatric social workers, and 3,400 psychiatric nurses. The demand is caused primary by a rising utilization rate. The shortfall drops for the three non-medical mental health professions. It worsens for psychiatrists because of declines in the supply of both U.S. and foreign medical graduates.

It should be noted that the existing supply of mental health professionals is not equitably distributed, and shortages are much worse in some geographic areas and types of mental health facilities than others. Accordingly, NIMH is requesting authorizations to require that those students in the mental health professions who receive NIMH support for their basic education later work for a period of time in shortage areas or with underserved populations. While NIMH provides stipends to only a fraction of all professional students, the payback requirement should make a real impact on maldistribution. Over 3,200 job vacancies in understaffed public facilities have been identified in a recent survey. At the same time because of the shortage of new psychiatrists NIMH must support projects which will make specialization in psychiatry a more attractive career choice for American medical graduates, as well as projects designed to give greater mental health skills and knowledge to primary care physicians so that they can better handle some of the demand for psychiatric services.

SUBCOMMITTEE RECESS

Senator SCHMITT. The subcommittee will stand in recess until 2 p.m. tomorrow.

[Whereupon, at 3 p.m., Monday, March 5, the subcommittee was recessed, to reconvene at 2 p.m., Tuesday, March 6.]

DEPARTMENTS OF LABOR AND HEALTH, EDUCATION, AND WELFARE AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 1980

TUESDAY, MARCH 6, 1979

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
Washington, D.C.

The subcommittee met at 2:10 p.m., in room S-128, the Capitol, Hon. Quentin N. Burdick presiding.

Present: Senators Burdick and Schweiker.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

HEALTH RESOURCES ADMINISTRATION

STATEMENT OF DR. HENRY A. FOLEY, ADMINISTRATOR

ACCOMPANIED BY:

DR. DANIEL F. WHITESIDE, DIRECTOR, BUREAU OF HEALTH MANPOWER

DR. JAMES A. WALSH, ASSOCIATE ADMINISTRATOR FOR OPERATIONS AND MANAGEMENT

DR. COLIN C. RORRIE, DIRECTOR, BUREAU OF HEALTH PLANNING

DR. FLORENCE B. FIORI, DIRECTOR, BUREAU OF HEALTH FACILITIES FINANCING, COMPLIANCE, AND CONVERSION

BUDGET REQUESTS

Senator BURDICK. The subcommittee will come to order.

This afternoon Dr. Henry Foley, the Administrator of the Health Resources Administration, is with us to discuss the 1979 and 1980 budget requests for HRA.

Dr. Foley, you are requesting that about $168 million be rescinded in fiscal year 1979, and your 1980 budget requests further reductions of $126 million. The committee is interested in hearing your reasons for these reductions.

INTRODUCTION OF ASSOCIATES

Would you like to introduce your associates for the record and present your opening statement?

Dr. FOLEY. Thank you, Senator.

To my left is Dr. Dan Whiteside, who heads the Bureau of Health Manpower. To my left and right is: Jim Walsh, my executive officer; Dr. Colin Rorrie, who is the head of the Health Planning Bureau; and Dr. Florence Fiori, who is the head of the Bureau of Health Facilities.

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If I could, I would like to try to summarize and then go right into questions with you, there are three parts of my statement. One is in terms of the rescission for this year, fiscal year 1979; second, the question of the supplemental; and the third item, the 1980 budget.

RESCISSIONS

As you have indicated, we are asking for a $168 million rescission for health manpower programs. We are asking for a $76,770,000 rescission in capitation grants for health professionals.

We are doing this primarily because we have taken the position that we are producing enough physicians, osteopaths and dentists in the country. We think the funding of education for this particular group can be supported through loans or increased tuitions. Costs that could be covered by loans, also by State assistance to students studying for these professions.

We have also requested a $10 million cut in student loans. But I would point out that here we have a revolving fund that the Congress and previous administrations and this one have funded to the medical schools, so that there is a situation where the medical schools will have approximately $14 million in the upcoming year from that fund to provide student loans to the students going to the medical, dental, and osteopathic schools.

We are requesting a significant cut in the area of nursing, specifically in capitation, advanced nurse training, special projects, student loans, scholarships, traineeships, loan repayments, fellowships, and research grants. We are therefore taking the position, in terms of the capitation grants for nursing, that we are producing an adequate number of nurses in the country right now within the existing capacity both at the baccalaureate level, diploma level and associate degree level.

We feel that the programs in the Office of Education, both the grant programs and loan programs, should be made available and students studying nursing encouraged to use those programs. And we are therefore recommending noncontinuation of the capitation grants for nursing.

In the area of advanced nurse training, special projects, we have taken the position that, due to budget constraints, we are not in a position to fine tune or enhance the capacity, the existing capacity that the Federal Government has helped to build in schools of nursing. Therefore, we have requested a fairly significant cut in that area as well.

In the area of student loans, we have requested a cut, with the recognition that we have a very sizable revolving fund in schools of nursing, in which we would still have, approximately $10 million in the upcoming year to provide to students of nursing.

We have recommended a cut in the area of research grants, primarily because of budget constraints, and feel that this particular area should be funded through the National Institutes of Health and the National Center for Health Services Research.

In the area of special education programs, we are recommending a fairly significant cut, on the assumption that State and local governments will pick up the funding, and also, on the grounds that we have funded approximately 92,000 health professionals, particularly physicians and nurses, in this area since 1974.

This was proposed to Congress as a demonstration effort. We think the time for that demonstration effort is past, and it is up to local and State government to pick up the resources. This is in the area of the rescissions.

We have also recommended a drop in authority, loan guarantee authority of $250 million, which we have not expended. And this would reduce by $108 million in interest subsidies for the construction of hospitals in the country.

In the area of the upcoming budget, we are basically proposing a budget that emphasizes a continuation in three areas: specifically in health planning, health facilities and health professions manpower. We are recommending that in funding for the health planning area there be a modest increase in the health systems agencies in the country as they now begin to pick up new activities, particularly around certificate of need activities at the local level related to state government.

We have recommended a cut in the centers for health planning, and we will suggest that we do the technical assistance to the State health planning agencies and the health systems agencies through HEW staff.

We are now past the establishment of these agencies and we are at a point to judge them in terms of their performance, and therefore the increase, given scarce resources, is modest from the President's standpoint and from the Department.

HEALTH FACILITIES

In the area of health facilities, we are recommending the continuation of the monitoring of the $3.5 billion of Hill-Burton loan assurances that we are responsible for as well as the 242 program of HUD. That is approximately $8,484,000. And we are asking in addition for $30 million for a closure and conversion program, which will result in a new program that we are proposing to the authorization committees; it would enable us to assist those hospitals which could be closed but because of financial barriers currently cannot close.

These would not be hospitals up for bankruptcy, but hospitals that could possibly merge or convert to other uses, and therefore help us save some money, both in terms of private reimbursement as well as public reimbursement.

In the area of health manpower, we are proposing a strategy which is consistent with the 1976 act that emphasizes an approach to try to meet the geographical distribution problems of health professions in this country and also begin to impact on the specialty distribution.

We have proposed a significant increase in training support for family medicine and primary care. We have proposed a relatively modest increase in the Health Service Corps, consistent with our approach to try to place health professionals in underserved areas of the country.

Hopefully, we will come back to the Congress with an approach from the administration that points to a full strategy for the National Health Service Corps up to 1990.

We have not taken the position to continue increased production particularly of physicians in the country. We recognize that the

studies done inside the administration as well as the Congress, the Congressional Budget Office and the GAO, show that we are producing enough physicians in aggregate, but not producing physicians for the right places in the country. Therefore we are emphasizing the programs in primary care, family medicine, as well as the National Health Service Corps.

We have recommended a relatively small budget for nursing, particularly in the area of special projects. In future years, when the budget situation may not be so constrained for the President, for the administration and the Department, we would hope to be able to suggest a modest increase in that area as well.

PREPARED STATEMENT

That briefly summarizes my statement with regard to both the rescission supplemental as well as the upcoming 1980 budget.

Senator, I will submit a more formal statement for the record.

Senator BURDICK. It will be received, without objection.

[The statement follows:]

STATEMENT OF DR. HENRY A. FOLEY

Mr. Chairman and Members of the Committee:

I am pleased to appear before the Committee today to present a proposed budget for the Health Resources Administration in Fiscal 1980 amounting to $466,433,000. These funds will enable the Agency to continue developing a national health planning capability to improve the decisions regarding allocation of scarce resources, and to promote innovative strategies and targeted development of the manpower, facilities, and other resources needed for an effective health care system. More specifically, the request includes funds to continue implementation of the National Health Planning and Resources Development Act and the Health Professions Educational Assistance Act.

Health Planning

FY 1980 marks the fifth year of operation for the Health Planning and Resources Development Program designed to improve the delivery of health services, contain costs, and improve the health of people through establishment of a nationwide network of Health Systems Agencies (HSAs) and State Health Planning and Development Agencies (SHPDAs) responsible for health planning in their areas.

A major focus of the planning agencies is to reduce the rapid increase in health care costs by influencing the number and type of capital investments made and the types of health facilities built. A recent study by the American Health Planning Association concluded that the HSAs and SHPDAs were responsible for capital savings of approximately $1.8 billion over a recent 24-month period. In addition, the agencies promote the development of alternatives to inpatient care, such as ambulatory and long-term care, which are generally less expensive but equally effective.

During 1980, 205 HSAs, 8 Section 1536 States and Territories, and 57 SHPDAs will be funded to cover each designated health service area and State in the Nation. By the end of 1979, approximately 190 HSAs will have completed their Health Systems Plans and Annual Implementation Plans and will be fully designated. We expect that most of the planning agencies will be fully designated by the end of 1980. With full designation, the HSAs will contribute

to the certificate of need process through reviews of new institutional health services, reviews of proposed uses of Federal funds, and reviews of the appropriateness of existing institutional services in their areas.

By the end of 1980, also, some 55 State agencies will be fully designated and completing State Health Plans, implementing certificate of need programs, and reviewing plans for funding under Federal health program allotments.

The 1980 budget request for these and the other activities in health planning amounts to $154,532,000.

Health Facilities

The new Bureau of Health Facilities Financing, Compliance and Conversion was created last year to promote the effective and efficient utilization of existing health facilities in the Nation, and to help promote cost containment by converting to other purposes or reducing the number of unnecessary short term beds.

The 1980 budget request for this program is $38,485,000, with $30 million of that earmarked for the conversion and closure program to be spelled out in legislation that will be proposed to this session of Congress.

The presence of unneeded facilities and services in the hospital sector is a major contributor to high and increasing costs of medical care. We estimate that there are 130,000 excess hospital beds in the Nation. The availability of such excess capacity tends to create its own demand, raising utilization without regard to the costs incurred, because of current hospital reimbursement incentives. Many States, third party payers such as Blue Cross/Blue Shield, and business and industry groups have recognized the excess capacity problem. Voluntary cooperation between hospitals and third party payers has resulted in the closure of some excess capacity, and several States have passed legislation regarding the development of closure programs. A significant impediment to these activities is the lack of funds to overcome financial barriers to closure. Our proposed Federal program is a demonstration effort to provide such financial aid. It is expected to encourage the closure or conversion of unneeded hospital facilities identified through the State

and local health planning process. Federal investment in such a grant program can be recovered, in part, from savings incurred each year in the reduction of hospital operating expenses.

The Bureau also will focus its resources on three other goals beyond cost containment: (1) assist in the development of HEW policy regarding health facility capital formation to help reduce unnecessary construction and the inefficient utilization of facilities; (2) encourage the enforcement of Federal requirements that facilities which have received Federal funding provide a reasonable volume of free care to persons unable to pay; and (3) actively monitor hospital facility loans and outstanding Health Professions and Nursing Construction loans and grants to ensure compliance with Federal requirements.

Health Manpower

Health professions education activities in FY 1980 will be focused on certain major priorities identified in the Health Professions Educational Assistance Act of 1976. These include: (1) increasing the availability of primary care through increasing the proportion of health professions students entering the primary care specialties, such as family medicine; (2) improving the geographic distribution of health manpower; (3) promoting increased utilization of health care extenders, such as physicians' assistants and nurse practitioners, to raise the productivity of health care teams and extend direct health care; and (4) improving health career opportunities for the disadvantaged.

The budget reflects a change in emphasis — from providing additional increases in the aggregate number of practitioners to providing an improved geographic and specialty distribution of health professionals. Earlier programs sought to increase the number of trained health professionals by providing financial incentives through Health Professions and Nursing Capitation Grants. Because of the increased educational capacities developed during those years, the number of physicians has increased 67,400 since 1970 - from 323,200 to the 1976 level of 390,600. During the same period the number of nurses increased by 289,000 -- from 722,000 in 1970 to the current level of 1,011,100. In addition, because of the long range economic benefits derived by most practicing health

professionals, students should assume more of their own educational costs, either through loans or a service-payback mechanism.

The major program aimed at improving the geographic distribution of health manpower is the National Health Service Corps Scholarships, which require one year of service in return for each year of scholarship support received. The program awards financial assistance for educational and living expenses in exchange for equivalent years of service in the National Health Service Corps, the Indian Health Service, or private practice in a health manpower shortage area. The budget request will provide support for 6,195 participants in 1980.

The request also will provide funds for the nurse practitioner program. Grants and contracts will be supported to plan, develop, and operate programs to train nurse practitioners in such fields as pediatrics, geriatrics, and working with nursing home patients.

Among the variety of special project grant and contract activities to tackle the problem of specialty maldistribution will be support for family medicine residencies and training, medical residency programs in internal medicine and pediatrics emphasizing primary care, and special educational initiatives within training programs for primary care physicians. These programs will address such problems as: environmental health care, preventive medicine, geriatrics, and nutrition education. The special project activities can help increase the number of physicians in family medicine and primary care practice as well as improve the primary care training they receive in medical schools and in residencies. In addition, continued support is proposed for public health and health administration traineeships and special projects.

Special project funds also are requested to support training programs for physicians' assistants and dental extenders, promoting the concept that certain health services can be provided adequately by persons receiving shorter and less costly training than physicians and dentists. An additional area of special project assistance is designed to recruit disadvantaged students into health professions training through identifying the disadvantaged

students and providing counseling and preliminary education. Funding also is requested for a program of manpower analysis which will focus on the forecasting of manpower supply and requirements, the improved designation of health manpower shortage areas, and monitoring of the impact of restricted entry of foreign medical graduates on the availability of health manpower.

The Health Professions Educational Assistance Act of 1976 expires at the end of 1980. We will submit a legislative proposal early in this session of Congress containing the Administration's recommendations for shaping professions training in the future.

I would like to point out that our 1980 budget proposal reflects our requested rescission of $168 million of FY 1979 funds for four health manpower programs that we feel are no longer required since program goals have been met and for which Federal assistance is no longer necessary, as well as our supplemental request that the total principal amount of loans to be guaranteed or directly made under Titles VI and XVI of the Public Health Service Act be reduced by $250 million from $1.75 billion to $1.5 billion.

Through all of our activities, in health planning, health facilities, and health manpower development, HRA hopes to make a significant contribution to the Nation's health care system and to the individual health status of Americans, with the funds requested for 1980.

NURSE TRAINING PROGRAMS

Senator BURDICK. Senator Schweicker, do your have any questions?

Senator SCHWEIKER. Do you want to say something, Senator Javits?

Senator JAVITS. May I, Mr. Chairman?

Senator BURDICK. Yes.

Senator JAVITS. I would like to say a word on behalf of these federally supported nursing programs, which I think we cut much too heavily in the President's program. I appreciate the President's problems, but as came out in testimony which we had at the Joint Economic Committee, Secretary Blumenthal admitted that the President in picking a parameter on appropriations budget, a $500 billion budget, leaving a deficit of $29 billion, chose his priorities.

Now, however, he agreed that the budget is in the hands of the Congress and that we have a right to choose our priorities. While I fully support the President's overall budget figures, in fact, hope

that we can reduce the deficit even further, I believe we too must have some freedom in terms of plotting our priorities.

I hope the committee, as the House has already indicated, will be more considerate of the nursing programs. They have been so successful. They have begun to reverse the trend of the real crisis, that is, a severe shortage in the supply of nurses. The nurses have certainly more than cooperated. Furthermore, nursing is a marvelous career opportunity for young people.

Without in any way trying to substitute my finite judgment for that of the committee, in which I have the utmost confidence, I just merely submit those thoughts, in the hope that the committee may ameliorate the rigors which the President's budget imposes on nursing education.

Senator SCHWEIKER. Senator Javits, are you talking now about the fiscal 1980 budget and the rescissions that we have before us?

Senator JAVITS. Both. That is exactly right.

I have introduced a bill with respect to fiscal year 1980, S. 230, which I ask unanimous consent may be made part of the record, so as to be before the members dealing with the subject, trying to reverse what seems to have been an OMB decision which led to a pocket-veto of a similar bill last year.

S. 230 is cosponsored by 29 Senators, including my colleague Senator Schweiker, who succeeded me as ranking member of the Human Resources Committee. That bill would extend the nurse training program for 1 year at an authorization level of $125 million.

So the detailed facts are before you. The current funding is $120 million.

The House Labor and HEW Appropriations Subcommittee approved a portion of the rescission request, which took $38 million of what was roughly an $84 million rescission. So there is plenty of room for trying to do justice mercifully.

Senator BURDICK. You referred to the other body. [Laughter.]

Are you aware that they cut this nursing program $38 million?

Senator JAVITS. Yes, but the President proposed cutting it by $84 million. I interpret the House action as a statement that the President's proposal is a cut of almost $50 million too much.

I wish only to stimulate your sympathetic consideration of these programs

Senator BURDICK. Thank you for the stimulation.

Senator JAVITS. Thank you very much.

Senator BURDICK. Senator Schweiker?

RESCISSION REQUEST FOR CAPITATION

Senator SCHWEIKER. Dr. Foley, what effect on college finance and operation or do you see resulting from your proposal to rescind $57 million in MOD capitation funds?

Dr. FOLEY. I think there is an implication in three areas. We would see—as you are aware, our suggestion for the cut in the medicine, osteopathy and dentistry capitation would move the current level of $1,339 per student to a level of $685. We would think that this would have to be taken up by either an increase of tuition for students in medicine, or an increase in those universities that

are funded by State tax dollars. There is the possibility of an increase in the amount of loans being made by those schools to students facing increased tuition.

The primary effect of this change would be an increase in the tuition to the students, and we think that that is not unacceptable. We are cognizant that students pay less than 5 percent of the total operating cost now for their programs in schools of medicines, and given the rate of return on their investment on the completion of their training in medicine, we think the increase is reasonable.

The average salary now of a physician in practice is $59,500 per year. We think that that is an acceptable guarantee to most banking firms, as well as other lending concerns, for funding.

ANNUAL COST FOR PENNSYLVANIA MEDICAL SCHOOLS

Senator SCHWEIKER. For the record, I would like to inject in the record what figures it would impact on. I have this, I might say, from Dean Stemmler, University of Pennsylvania Medical School, who has provided me the information for the other medical schools in Pennsylvania.

They estimate that it will mean elimination of about $1 million per school, or close to $8 million. And interpolating that into tuition, from their calculations, they project that tuition would increase somewhere between $2,000 and $2,500 per year and that the yearly cost of student education would then range from $12,000 to $15,000 per year.

Obviously, you must not agree with this figure.

Dr. FOLEY. No, with respect to tuition, I would agree with the yearly costs you are suggesting for tuition and living expenses. The base that some of the students are paying in schools in Pennsylvania, if he is referring to the State schools as well as the private schools has been fairly low. Does the $12,000 include tuition and living expense? Then that figure comes close to ours.

Senator SCHWEIKER. That is correct.

Dr. FOLEY. We would agree with those figures.

Senator SCHWEIKER. All right.

Dr. FOLEY. Our figures are $12,000 to $13,000, so they are a little bit higher in the dean's State, but that is an acceptable range.

COST OF MEDICAL SCHOOLING

Senator SCHWEIKER. I gather you made the assumption that we can't cover everybody with National Health Service Corps scholarships. Even though you would make a modest increase in the scholarships it would cover, what, 25 percent of the student body?

Dr. WHITESIDE. It's not that high. It is less than that.

Senator SCHWEIKER. Less than that?

Dr. WHITESIDE. Much less than that.

Senator SCHWEIKER. Then you come back to the fact—and, of course, we had this come out in our health subcommittee hearings—that the person who takes advantage of the student loan program to participate with the present 12-percent interest rate will be in debt $140,000. That is within 3 years after graduation.

Isn't that imposing an intolerable burden on people who want to be doctors? I can see people saying, "I foreclose that possibility because I can't handle $140,000 of debt."

Dr. FOLEY. I think if what we were assuming that would affect all of the students in the medical school, we would share your concern.

Senator SCHWEIKER. It won't affect the rich ones. We can eliminate the rich ones.

Dr. FOLEY. It won't affect those students who will be using the revolving fund. Approximately $370 million has been loaned to date and each year it comes up with an additional $12 to $14 million that would be available to the students based on the decision of the medical school itself. So they would have that pot of funds, plus the HEAL program you are referring to, as well as alternatives through the banking community. We think that is an acceptable way to go.

STUDENT LOAN REVOLVING FUND

Senator SCHWEIKER. Which way are you saying is the best way to go?

Dr. FOLEY. You have the revolving fund. Since 1964 we as a country have been putting funds into that program. Previous to this year we put $20 million in, and this year we are recommending that the size of that revolving fund is great enough and the default rate is so low—1-percent default rate—that basically that fund is available to or open to the students to use at the discretion of the medical school itself.

Senator SCHWEIKER. What percentage of the students do you estimate would have an opportunity to participate in that program?

Dr. FOLEY. 13,000 students, approximately, would be eligible for that program in 1980.

Senator SCHWEIKER. Out of how many?

Dr. FOLEY. 65,000 medical students.

Senator SCHWEIKER. If the figure then isn't $140,000 that they owe, what will it be after they complete their program?

Dr. FOLEY. We would be glad to come back and have that multiplied out. It is a 7-percent interest rate. We have no record of default so far. The track record on that particular program is indicative that students who are using it are able to pay back when they get finished because the key criterion there is that we are not getting defaults.

Senator SCHWEIKER. How soon must they pay it back?

Dr. FOLEY. Within 10 years.

Senator SCHWEIKER. I knew I was missing something here. This ceiling is only $2,500 per year that they can borrow, and here we are talking about costs of $12,000 to $15,000 per year.

Dr. FOLEY. I think as——

Senator SCHWEIKER. I knew there was some element we were missing.

Dr. FOLEY. It is tuition plus $2,500. Tuition fees plus $2,500 is the ceiling as of 1978.

Senator SCHWEIKER. Tuition plus $2,500.

Dr. FOLEY. Yes. Tuition fees and $2,500.

Senator SCHWEIKER. Is that a change?

Dr. FOLEY. That was changed with the 1976 act, Senator.

Senator BURDICK. Is there a range for tuition?

Dr. FOLEY. Yes, there is. In the private schools, Senator, the average is $5,000. The range——

TUITION COSTS

Senator SCHWEIKER. Tuition, now?

Dr. FOLEY. Yes.

Senator SCHWEIKER. Not living?

Dr. FOLEY. No, not living expenses. The range will go from $2,200 to $9,140, in private schools.

Now, in public schools, the average for a resident is $1,428; and a non-resident, $2,939. The range for the resident there goes from $334 a year to $3,150; and for the non-resident, from $1,025 to $7,150. And that is why we have in our testimony in the House and here, stated very strongly that this is a very low tuition that students are paying to enter a profession that has a tremendous rate of return. It is extremely low and could be raised without significant impact on the numbers going into medical schools at this time. We see the retention rate of the medical schools well above 95 percent. We see little default in terms of loans that they have taken out, even if they had gone the private sector route, rather than the governmental. And we see no lack of demand for the number of slots in medical schools. There are almost three applicants for every slot we have.

EXCEPTIONAL FINANCIAL NEED ELIGIBILITY

Senator SCHWEIKER. I don't argue that.

In terms of demands for slots, that's true, but the question is what chance does a middle-income student have to get in it? Because it seems to me that two people have chances: the rich and the poor ones who qualify for these programs.

This is the program you just described; I have a budget backup sheet here and it says eligiblity is conditional on a demonstration of "exceptional financial need."

What is "exceptional financial need"? And, again, middle America gets it right in the neck because I am sure that they can't demonstrate that. What is it?

Dr. WHITESIDE. We have proposed in our regulations that "exceptional financial need" be defined in such a way that the financial aid officers do a need analysis based on the resources available to the student and to the family, and you can start with the students whose families' incomes is such that they would not be reasonably expected to contribute to that individual's education, and you start at that point and go as far through funding students as it would be possible for the funds to cover. You start with the neediest and work on through.

Senator SCHWEIKER. You have some figures in terms of what kind of income test this is? That answer doesn't tell us very much.

Dr. FOLEY. We would be glad to supply that for the record.

[The information follows:]

Needs analysis systems are recognized by the Office of Education and the financial aid community as a viable methodology to determine the financial need of students.

In determining the amount of support that a parent would be expected to contribute toward the student's education, the needs analysis service takes into consideration the amount of income, amount of taxes, indebtedness, sickness expense, number of dependents, and normal maintenance and support of family. Thus a family with an income of $16,000, with 5 children would not be expected to contribute to the student's education while a family with 1 child and earning $9,000 would be expected to contribute to the student's support. Therefore, it is not just the income level that determines the amount of support by the parent.

DEFAULT RATE

Senator SCHWEIKER. I think it would be very helpful. It gets into the area whether you are robbing the vast middle group of the opportunity to go to medical school because they fall between the two cracks of being very rich or simply able to qualify for these programs.

You say your default rate is how low?

Dr. FOLEY. One percent.

Senator SCHWEIKER. One percent. We better get you to tell the other people how to operate their programs. [Laughter.]

You are doing something right on that score. I have to give you credit. I wish it was contagious.

Dr. FOLEY. I think it is not only us. I think it is the medical schools themselves and the dentistry schools and schools of osteopathy.

TYPES OF FINANCIAL AID

Senator SCHWEIKER. Would you give us a breakdown? I guess what I am asking for is what percent of the present student body do we expect to avail themselves of the different options that are available. In other words, how many will have to have private support, how many will come under the HEAL program, how many come under the other loan programs, how many come under the Service Corps program. I would like to see a percentage estimate of what this means and, in essence, what percent then has to do it on their own or incur their own debt at this point.

Dr. FOLEY. We will give that to you. You are concerned—and I understand it—you are concerned with the middle class, because we have identified programs for the disadvantaged: We have the scholarship programs plus the National Health Service Corps, which is also open to the middle class as well, plus the HEAL program.

Senator SCHWEIKER. What percent is it you can take? You say it is less than 25. I was apparently too high.

Dr. WHITESIDE. About 7 or 8 percent.

Dr. FOLEY. We will give you a breakdown of what we would have as a guesstimate in each of these categories.

LOAN PAYBACK

Senator SCHWEIKER. Would you also include in that—I gave you $140,000; I think that is the calculated figure for the other student loan program. But I would like to have the same payback for your HEAL program and see what they are.

I think one key question here is that you come out with a debt of $100,000 under your smaller loan program, or $150,000 under your big loan program. Doesn't that push people into the high-pay specialty range, the very range we don't want them in? If I saw a bill of $100,000 that I owed as soon as I got out of school, what would I do? Instinctively, I want to pay that off, and instinctively, I am going to go to where the highest rate of immediate return is so I can get that off my back, to raise my family and do my thing. And doesn't that just push everybody to where we are trying to get them away from, which is your high-paying specialties?

Dr. FOLEY. I would suggest just the opposite: If I were a student finishing my 3 to 4 years of medical school with that type of debt and now was going to add 3 to 4 more years of specialization on it and increase that debt and still have the responsibility to pay back for those 3 to 4 years, then that would be a deterrent for me to go on to some specialty. I might want to get out and practice in primary care, into the field quickly, rather than continue to accrue debt. It may be the incentive system is working in the opposite direction.

MEDICAL SPECIALIZATION VERSUS DEBT

Senator SCHWEIKER. Do you have statistics showing where those people in fact are going, into what specialty they go? Would that be available or not?

Dr. FOLEY. In each of these particular programs?

Senator SCHWEIKER. Yes.

Dr. WHITESIDE. We don't have it readily available in terms of specialization related back to the amount of debt that they have. We might be able to get some information on it.

Senator SCHWEIKER. I don't want to make a burden on procuring information, but if it is available by punching a computer button—you may be right, I don't know. It raises an interesting question.

[The information follows:]

Based on an Association of American Medical Colleges study of medical student financing for 1977-78, it is estimated that first year medical students would finance their education as follows:

3 percent receive an Exceptional Financial Need Scholarship.

7 percent receive a National Health Service Corps or Department of Defense Scholarship.

20 percent receive a Health Professions Student Loan.

19 percent receive a Guaranteed Student Loan.

17 percent receive other loans—Health Educational Assistance Loan program, Robert Wood Johnson, American Medical Association and State.

School Year 1979-80

Discipline	Enrollment [1]	Number of National Health Service Corps scholarships [1]	Percent of total enrollment
Medicine	60,000	4,395	7.33
Osteopathy	4,000	622	15.55
Dentistry	22,000	558	2.54
Optometry	4,500	6	0.13
Pharmacy	31,000	6	0.02
Podiatry	2,500	106	4.24
Veterinary medicine	7,000	63	0.90
Total	131,000	5,756	4.39

[1] Estimated.

LEADTIME OF 7 YEARS

There is generally a seven year lead time before physicians begin their obligated service in the National Health Service Corps. Significant numbers of physicians have not begun practicing yet, therefore, the information is not available.

Dr. FOLEY. I have heard the argument about the other side. I have thought about that rather carefully. If I were facing 7 years of debt, rather than 4, I might very well want the 4 years of debt, rather than the 7.

In your figures that you gave us from the University of Pennsylvania, could you ask your staff to provide that? What I find interesting is that the increase they are suggesting is greater than the capitation dollars provided to the State.

Senator SCHWEIKER. As I said, the figures don't agree with yours. These were put together by the deans of medical schools who meet periodically, and with whom I meet. I would like to reconcile the apparent differences.

Dr. FOLEY. We would be concerned if the argument is that our decreasing of capitation in the Federal Government side is going to cause a greater increase in tuition costs or State funding. We would like to know what the margin is to explain that difference. This is the first time that has been presented to us.

ELIMINATION OF CAPITATION PROGRAM

Senator SCHWEIKER. Let me tell you where I think one difference is: Those figures were based on the elimination of capitation rates.

Dr. FOLEY. Is it a dollar-for-dollar substitution for the elimination of capitation?

Senator SCHWEIKER. This is a complete elimination. We are not talking about rescission; we are talking about complete elimination.

Dr. FOLEY. Our figures, basically, for the rescission——

Senator SCHWEIKER. But the two figures you gave me, the figures of $1,389 and $685——

Dr. FOLEY. The $685 is the reduction in 1980. We are suggesting a $654 reduction in the rescission leaving $685 in 1979 if it is the 1980 figure, then it is——

Senator SCHWEIKER. What is the 1980 figure? Our figures are 1980 figures. Our figures are based on what you are projecting for your 1980 budget, which is no capitation grants. What is your figure for that? That is not $685.

Dr. FOLEY. $1,368 per student in 1978, $685 in 1979, and zero in 1980.

Senator SCHWEIKER. You said that is your 1980 budget projections.

Dr. FOLEY. Yes, sir. If we could do this, Senator, get our staff together with yours and talk over which per student we are talking about, which is the base year. We are concerned, as you are.

CAPITATION FOR VOPP'S

Senator SCHWEIKER. All right, let's get the facts together and not prolong the questions on that.

You also, then, intend to wipe out the VOPP programs as well. What is the rationale there? In addition to the MOD programs.

Dr. FOLEY. The basic rationale in terms of the VOPP is, in terms of our priorities in the numbers of students going into these programs, that there is not the need for Federal support for veterinary medicine, podiatry, pharmacy and optometry. So, we have recommended basically an elimination of the funding for those programs.

REAPPROPRIATION OF CAPITATION FUNDS

Senator SCHWEIKER. Under what authority do you propose transfer of the $7½ million from the VOPP capitation program to the Indian Health Service?

Dr. WALSH. Senator, this would be proposed as a reappropriation.

Senator SCHWEIKER. Reprograming?

Dr. WALSH. Reappropriation, assuming that the rescission request is approved.

Senator SCHWEIKER. One of the complications that we see is, of course, this is the Labor-HEW bill, and you are proposing putting it in the Department of the Interior appropriations bill.

Dr. WALSH. That is why I used the term "reappropriation." It is a technical matter, but strictly speaking, the reprograming would not do it; you are correct. The Indian Health Service is not within this appropriation, so we would have to propose to the Congress—and we are, through this proposal—that the $7.5 million be reappropriated.

Senator SCHWEIKER. When you say "reappropriation," do you mean a new appropriation?

Dr. WALSH. That is my understanding.

Senator SCHWEIKER. We are together on that, at least in terms of your method.

NURSING PROGRAMS

Doctor, you heard Senator Javits argue on behalf of the nurses. Why do you want to phase down nurses? Why this great discrepancy between experts who say that: We do need nurses; we don't nurses; we have plenty of nurses; we don't have enough nurses? Why can't we reach some agreement on what we need in terms of our health people?

Dr. FOLEY. We have reached an agreement between the Congressional Budget Office and, surprisingly, this administration. We are both in agreement that we are producing enough numbers over the 15 years in the area of nurses.

We are producing, in the registered nurses per year, 78,000. Without national health insurance, that seems to be an adequate number of nurses. It does not solve the question of specific shortages in different parts of the country, and that is why we have recommended that certain programs like the National Health Service Corps be expanded for the nurses to meet that particular problem.

We have not recommended a decrease in funding in the Office of Education for nurses. In fact, what we have done is recommend to the grants and aids officers in the schools of nursing, that they avail themselves of the five grant and loan programs in that au-

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thority so that nurses at the undergraduate level can have some student support.

The numbers game that has been played I find interesting, since everybody seems to be quoting the same source documents.

Senator SCHWEIKER. That's right. That is why I raised the question.

Dr. FOLEY. The figures are clear. What we have seen are people saying that if we have national health insurance, we will need a greater number of nurses than we are producing right now.

There is a problem with that. One is whose national health insurance proposal? What are the parameters of it?

And, second, even if we were to have national health insurance passed and implemented, let's say, in the middle 1980's, we would have at least 2-year start-up time to be able to expand the number of nurses in schools, particularly at the community college level and at the baccalaureate level.

We have not recommended a decrease of basic access for students to go into nursing. In fact, we find that the average lifetime, working lifetime for a nurse, is 30.1 years. Nurses generally tend to practice for 8 to 10 years, then go out of practice for approximately 10 years, and then come back into the work force.

At any point in time, the figures range from—in different parts of the country—25 to 35 percent of the nurses being out of the work force.

What we see is an adequate number of nurses, but what we haven't seen is an adequate number in specific areas of the country. We think we need to go with targeted programs to bring nurses into those specific shortage areas, as we have done with the nurse practitioners and what we would do in terms of the National Health Service Corps.

I think we should be clear about the capitation area. We are not closing off the opportunity to students at the undergraduate level to avail themselves of funds in the Office of Education to support their training.

Senator SCHWEIKER. How much is that?

Dr. FOLEY. It depends on the particular loan program. I think it would be greater than what we are currently paying in capitation.

Right now, we pay per student—depending if they are in an associate degree program or in a bachelor program—anywhere from $140 to $162 in capitation.

I think it is becoming a symbolic issue, rather than a real substantive issue. We are recommending that the funds provided through this committee, as well as other committees of the Congress, be used through the Office of Education for students training to become nurses.

HEALTH CARE SHORTAGE AREAS

Senator SCHWEIKER. Coming back to the National Health Service Corps for a few minutes, how many new students must be supported each year by the National Health Service Corps scholarship program to correct the imbalance that we see in the shortage areas? How many years and how many students are we talking about?

Dr. FOLEY. If we assume no migratory changes of physicians into certain areas—which would be the wrong assumption—physicians will move into the area, or nurse practitioners, without the National Health Service Corps.

That aside, we currently have 1,233 primary medical shortage areas, and we would need 7,785 primary medical physicians for those areas.

If we assume all of the definitions that have been discussed with the Congress of what are considered health care shortage areas, we would need approximately 16,000 physicians by 1990 to cover those areas.

RECIPIENTS OF FINANCIAL AID

Senator SCHWEIKER. 16,000. At the rate we are dispensing scholarships, how much of that need are we going to meet?

Dr. FOLEY. Currently—I think we have 6,195 total recipients. Not all of those are physicians, although 90 percent of them are.

We would have to—once we get past these rather tight budgetary years—expand the number of slots to meet the call.

Senator SCHWEIKER. You have to go from 6,000 to 16,000? Is that a cumulative figure or yearly?

Dr. FOLEY. No, we are suggesting something more complicated than that, not that everyone would go in the National Health Service Corps, but physicians trained for family care and primary medicine—that have a likelihood of practicing in those areas—that they would continue to move into those areas so that the strategy is not only the funding of the National Health Service Corps, but also of the support of primary care and family medicine as well.

Our figures range around 6,000 physicians coming out to the Corps by 1990, plus the difference being made up by the physicians coming out of primary care and family medicine, as well as physicians moving into these areas of their own volition.

UNDERSERVED AREAS: SUPPLY VERSUS NEED

Senator SCHWEIKER. When do you expect, that the number of health professionals going into underserved areas will be in the right proportion to the number of people living in such areas? Do you have a prediction on that?

Dr. FOLEY. I don't think we do, but we would sit down and try to work that out if possible.

Senator SCHWEIKER. Wouldn't that be the goal? Isn't that our goal?

Dr. FOLEY. Yes, it is. We have looked at the turnover rate. What we are cautious about is that certain turnover rates in certain parts of the country can change as populations expand in those areas or new industries develop.

It may become attractive for people to stay in that area. For example, in the Wyoming area, as they have expansion in their coal industry, it may be that the population growth will be sufficient that specialists and others will want to stay in these particular areas.

Senator SCHWEIKER. I am not clear on one figure. Maybe it is a tough figure. How many graduates must we turn out in the Nation-

al Health Service Corps program to meet what we perceive as an underserved area?

Ms. WORMSER. May I try to answer that?

It may be a tough question. It is a question still under consideration. We regard it as one that will be addressed in the 1981 budget cycle—that is, of a future-year funding problem.

The question is: Given the need that is out there, how much of that need is going to be met by the normal output of physicians, the choices that they themselves make?

What we are finding is that—among at least family medicine graduates—they are choosing to settle more and more in non-SMSA areas. If that trend continues, then the free market will meet the need that you are talking about.

And to that extent, the need for National Health Service Corps-trained physicians will diminish. They are, as you know, a very expensive resource.

Senator SCHWEIKER. Are you saying that if the present rate continues, it will meet this need? I am not clear whether you are saying that we are on an up-curve, and if that up-curve continues, we will meet it; or are you saying that the rate of entering the underserved areas now—that if that continues, we will meet it? Which are you saying?

Ms. WORMSER. We are saying the very preliminary data seems to indicate that the rate of location in underserved areas is blank and that we need an opportunity to look at that some more and see if the trend continues and whether the need in the underserved areas can be met by that normal outflow.

Senator SCHWEIKER. Does that mean that the present rate must keep increasing? Or does it mean that if we keep the same rate with the ensuing classes—which is it?

Ms. WORMSER. I believe it is the same rate thus far.

Senator SCHWEIKER. There is a substantial difference.

Ms. WORMSER. Yes, it is.

GEOGRAPHIC LOCATION OF FAMILY PRACTICE GRADUATES

Senator SCHWEIKER. Could you give us something for the record as to what you see realistically occurring, or what you hope would occur?

Ms. WORMSER. Yes.

[The information follows:]

According to data obtained from the American Academy of Family Physicians on February 23, 1979, the following data are provided regarding the initial practice locations of family practice residency graduates for 1977 and 1978 by community population size:

Graduates surveyed in 1977, 1190; graduates surveyed in 1978, 1548.

	Percent	
	1977	1978
1. Rural Area or town of less than a population of 2,500 not within 25 miles of a large city	11.1	8.4
2. Rural area or town of less than a population of 2,500 to 25,000 not within 25 miles of a large city	2.7	3.1
3. Rural area or town of 2,500 to 25,000 population not within 25 miles of a large city	24.7	23.8

	Percent	
	1977	1978
4. Rural area or town of 2,500 to 25,000 population within 24 miles of a large city	14.7	16.9
Subtotal	53.2	52.2
5. Small city 24,000 to 100,000	17.4	17.2
6. Suburbs of small metropolitan area of 100,000 to 500,000	1.8	3.5
7. Small metro area 100,000 to 500,000	10.7	8.3
8. Suburbs of large metro area over 500,000	7.5	9.5
9. Large metro area over 500,000	6.2	6.7
10. Innercity or low income area within city of 500,000 or more	3.2	2.6
Total	100.0	100.0

SHORTAGE AREA RETENTION RATE

Senator SCHWEIKER. I have two more questions, Mr. Chairman. The GAO study showed that many National Health Service Corps physicians that were placed in the shortage areas were underutilized, and the retention rate was very poor.

And so even though we got them there, we weren't using them properly, and they weren't staying.

My question is: How do we solve that problem? And isn't that contradicting the whole program?

Dr. FOLEY. I think we are in the process of solving the problem. The GAO study is based on 3-year old data. Part of the problem was getting the physician placed in the community and building up his practice.

Oftentimes the clientele in the area has to be built up. It is basically potential and has not started to use the services. So we found that the physicians were not being used as much as they could have been.

We have recently put the National Health Service Corps into a productivity frame and increased the pressure on them, basically to provide services to those populations that need services. And we think that that problem is being resolved.

The second problem though, which is the attrition rate, is that you do have a turnover, because some areas are not all that attractive to the physicians and spouses to stay in. And we expect the cycling effect in some areas of the country. We don't expect that all physicians will want to stay in the areas that we place them.

What we have tried to do, through efforts like the area health education centers, is to link physicians we place in these rural and urban shortage sites so that they have linkages back to their other colleagues and professionals. They need to have a sense of a support system so that they will want to practice in these areas, still having the different, ongoing, in-service training that is available through the tertiary care centers.

So we are taking steps to provide both moral and professional support to National Health Service Corpsmen. We think that the attrition rate will decrease because of these efforts.

We have seen some minor decreasing of that now, and we are increasing the productivity of those physicians, the longer they stay at the site.

AREA HEALTH EDUCATION CENTERS

Senator SCHWEIKER. You just led to my next question.

I agree with the point that you are making about the area health education centers; I have been an advocate of these, particularly for the rural areas, where we haven't got our real share. States such as the chairman's and mine are examples of this. And you are proposing a reduction from $20 million in fiscal 1979 to $5.8 million in fiscal year 1980. The AHEC's are one of the incentives, one of the reasons to get physicians to go in rural areas, because they have a clinical support facility and referral network that gives them continuing education and career opportunities.

I am disappointed, and wonder how you reconcile that budget cut with the need to create some incentive for physicians to make their careers in rural areas.

I realize that was probably an OMB cut instead of yours, but I would still like to hear the rationale behind it.

Dr. FOLEY. Senator, as I think you correctly pointed out, it is a phase-down. It is not a phase-out. We are not abandoning all the concept or the approach of the area health education centers.

Senator SCHWEIKER. We ought to be increasing it for the very reasons you eloquently cited a moment ago. [Laughter.]

Dr. FOLEY. Senator, you are a master—given constraints on the resources we had, we had to basically go with a reduction this year. That does not close off our options in future years, particularly as we see those area health education centers which are more effective than others.

We have dropped a couple of area health education centers this past year, one in the Southwest and one here, very close, because we did not see them meeting the conditions set by the Members of Congress and signed into law by the President. So we know that we have some margin within that budget for the existing area health education centers and perhaps even some new starts.

We would hope that as that program has improved in its performance that we are able to make that case both inside the administration and to Congress in other years, but this year we have lived within a strategy around the budget which has said services first.

We have expanded, as the Assistant Secretary will testify tomorrow, the services in the migrant health centers and the neighborhood health centers. And as a result, areas, even if the program is a good program, as I think AHEC's are, I will not suggest it for expansion or even a continuing level, as we have had this past year.

Senator SCHWEIKER. It was found that the most important factors in determining location of physicians are contact with other physicians, clinical support, and continuing education opportunities, which is just what AHEC provides. We are making the same point.

Thank you, Mr. Chairman.

Senator BURDICK. Fine.

HEALTH PROFESSIONS CAPITATION

Getting back to capitation, it seems to me that we are cutting the rug out from under our schools who have been promised these funds and have put them into their planning. Now, in the middle of the school year, they are left without funds.

How do you explain that or answer that to the school officials?

Dr. FOLEY. We are not cutting funds in this existing school year.

Senator BURDICK. I am talking about the rescission.

Dr. FOLEY. The rescission does not cut funds in this current school year that students are now in. I think that point has been overlooked. It does cut the funds for next year, beginning in September.

We have suggested—we think that there is adequate preparatory time for the grants and aid sections of the universities to reach out to the students studying to be nurses to avail themselves of the scholarships and loan programs under the Office of Education.

We were very conscious about not cutting them in this existing academic school year, for the very reason that you have indicated.

Senator BURDICK. September causes a problem because in many States, you have legislatures meeting now. A lot of them have already met, and they won't be in a position to help with State aid. So, the leadtime isn't very great.

Dr. FOLEY. It is not for those States now out of session. I think there are three to four that have gone out of session recently.

Senator BURDICK. Or at the tail end of their sessions.

Dr. FOLEY. Correct. We would then say that the alternative clearly is the use of the Office of Education funding which would not involve State government in terms of its use.

Senator BURDICK. Do you foresee any schools facing serious financial difficulties or foreclosure because of this loss of capitation funds?

Dr. FOLEY. There was testimony before Senator Kennedy, Senator Schweiker's committee, about approximately a month ago, and I believe there were two schools mentioned as perhaps being in serious trouble if the capitation were cut for nurses. We have looked at those schools. In one case we think that the school's State which is still in session could meet the funding needs of that school. The second school that was indicated as having problems has problems with regard to accreditation and retention of their existing number of students, even with capitation. We think the problem is not so much the capitation question as what is going on in the administration of the program itself in that university.

The bottom line is we do not have an indication that schools will go into bankruptcy or face severe fiscal difficulties at this time. We have asked that question. We do recognize that some parts of the nursing programs, depending on what cuts were accepted by the Congress, would affect perhaps some of their program efforts. They would have to cut back in the short run.

ALTERNATE FUNDING SOURCES

Senator BURDICK. What are we going to do about the schools that have made plans for the fall of 1979? What are we going to do

about them? They have relied upon these payments, and it is too late to make any changes. What do they do?

Dr. FOLEY. I think that they face the choice of raising the tuitions to the students, and having the students then avail themselves of the scholarship or loan programs, or economizing in their programs and cutting back in certain areas and maximizing that which is basic in the training of the nurses.

They face the same choices that many of us face in our household budget as we face cutbacks in certain areas, or increased inflation, et cetera. We think they face that problem, and we share a concern about it, but we think that they can manage it.

Senator BURDICK. Say they are relying on this appropriation until October 1 of this year and that is the appropriation year; now they are caught short on September 1. So, to that extent, you have created budget problems for them.

Dr. FOLEY. I understand that, Senator. Had we other choices in terms of the total budget for the administration, perhaps we could have ameliorated that. Clearly, we faced a very severe situation in terms of the deficit, and this particular area, along with several other areas, have had cutbacks. We recognize the problems they have in their planning processes, particularly around State legislatures and the budget processes in those legislatures.

FEDERAL ASSISTANCE TO NURSING SCHOOLS

Senator BURDICK. What is the basis for your statement in the justification that "There is no need to provide direct Federal assistance to increase the educational capacity of nursing schools"?

Dr. FOLEY. Senator, this country, particularly since 1964, has been expanding the number of nurse training programs in the country. We have seen an increase in the baccalaureate programs in nursing and in community college programs, not only with HEW funds, but Labor funds. We think that that capacity—and the data shows it—that, that capacity exists out there. It is not a problem of the production of the number of nurses; it is a question of where they are practicing in the country. We do not see this as a cutback in the production factor currently. We don't see any evidence that the community colleges will cut back their programs and particularly no evidence that the B.A. programs will cut back their programs.

In fact, we have seen diploma programs decrease in the country, becoming part of the baccalaureate programs, in many of the universities. And we think that, that trend will probably continue.

We would also suggest that perhaps we ought to relook at the diploma programs that we moved quickly away from over this past 10 years. Since diploma programs are reimbursed by medicare and medicaid and other third-party payments they provide an access point for the production of nurses in this country.

It is not simply the universities or community colleges that can produce nurses. The diploma programs within hospitals can do so also.

GEOGRAPHIC DISTRIBUTION PROBLEM

Senator BURDICK. You mentioned that there wasn't a shortage of nurses but it is a problem of distribution. Will your agency be able

to do anything to remedy this situation of geographic distribution, particularly to increase the number of nurses in the southern States, rural communities, and innercity neighborhoods?

Dr. FOLEY. We have recommended no rescissions in the nurse-practitioner program which addresses the geographic problem. We have every indication that shows us the nurse-practitioners do in fact move into these particular rural areas as well as the urban underserved areas. We would continue that program, and, as I indicated before, we would continue the expansion of the National Health Service Corps to nurses if funds permit, as the Secretary testified.

TARGET FUNDING TO UNDERSERVED AREAS

Senator BURDICK. Instead of the rescission of all nursing capitation funds, has your agency considered targeting funds to the nursing schools in or near the underserved areas?

Dr. FOLEY. We have funding similar to that, Senator, under consideration inside the administration for a proposal to the Congress. The existing law does not allow us to target it quite as the question indicates, so we would have to recommend some changes in either the nursing legislation or, if it becomes part of the health professions, in that particular piece. And we will have a proposal up here by August of this year. I hope that that area will be favorably considered by the administration. We think it is consistent with targeting our resources to get the nurses into underserved areas.

Senator BURDICK. Do you think the geographic maldistribution of nurses could be reduced by restricting loans, forgiveness options, to service in shortage areas? Do you think that would help any?

Dr. WHITESIDE. We currently have provisions that allow repayment of nurses loans if they simply stay in practice, which has been a provision that nurses have availed themselves of considerably. If you restrict it simply to shortage areas for nurses, I think that might have some positive effect in encouraging nurses to go into areas to practice where they have a shortage of nurses.

Senator BURDICK. You think it might have some good effects, then?

Dr. WHITESIDE. Yes, sir.

ADVANCED NURSE TRAINING

Senator BURDICK. In North Dakota, our nursing schools are depending on advanced nurse training money to upgrade the academic level of their faculties. This is necessary just to maintain accreditation. If these schools lose accreditation, they might well close, and rural North Dakota, which already needs nurses, will face a greater maldistribution problem than they do now.

Can you comment on how you envision schools in this situation can maintain their accreditation?

Dr. FOLEY. If the present teachers are not qualified, I think that assumes, Senator, that the States will not substitute the funding that we have been giving through the advanced nurse training for this particular activity. We would encourage the States to look at that rather critically. I think there is a danger that if we were to lose qualified teachers, that we might see a dimunition in the

quality of education in those schools. We are concerned about that. We would try to work with those schools to insure that that would not happen.

We think in an area where there is no question of the need for nurses—that there is a job market for nurses, that it would be to the State's advantage, particularly in State universities, to make sure that positions for faculty members in nursing be continued in contrast to some other areas such as of the liberal arts where there does not seem to be a market for graduates.

There has been a cutback over the last few years in terms of those particular faculty slots. We would think that the States, as well as private universities, might want to look very carefully at the subsidizing of or payment for faculty slots in departments where they know the students are going to find jobs when they come out of the university.

Senator SCHWEIKER. I have a question by Senator Mathias.

Senator BURDICK. Go ahead.

FUNDING SOURCES FOR NURSING RESEARCH

Senator SCHWEIKER. Given the president's rescission request of $3,899,000 for nursing research grants, has the Health Resources Administration devised any plans with NIH or the National Science Foundation or other potential funding sources to make up this loss?

Dr. FOLEY. At this moment in time, we have not. I began discussion yesterday with some nurses, and will begin to meet with Dr. Fredrickson, to try to arrange some linkage to the research community.

In the discussion I had with a couple of the deans, they identified some research projects that clearly could be funded under other authorities over at NIH if the protocols were acceptable in the peer review process. I would want to discuss that with Dr. Fredrickson, to see if that could be done.

Senator SCHWEIKER. After the House actions a moment ago, it may be moot.

Dr. FOLEY. Even in light of the House action, I am not predicting what the future may hold. I think it still is important that qualified nurses whom we have helped to train in this country be able to be used. They should be able to use the resources that are in NIH, as do other types of scholars, to obtain grants, particularly in the areas that have high priorities, such as gerontology, child, maternal health. I think it should be done, anyway.

Senator SCHWEIKER. Thank you, Mr. Chairman.

NHSC SCHOLARSHIPS TO NURSING STUDENTS

Senator BURDICK. How many NHSC scholarships have been awarded to nurses over the past few years, and how many are expected to be awarded to nurses in 1979 and 1980? I want to get a sort of curve.

Dr. FOLEY. We had awarded last year 160 scholarships to nurses. We proposed 180 this year and about the same number in 1980.

Senator BURDICK. Can you break it down per year?

Dr. FOLEY. Yes, Senator.

Senator BURDICK. For a 10-year period, and you can see the trend that way.

Dr. FOLEY. Senator, we have not supported nurses for 10 years. But we will do it as long as we have supported them.

[The information follows:]

NUMBER OF NHSC SCHOLARSHIP AWARDS TO STUDENTS IN BACCALAUREATE AND MASTER'S DEGREE PROGRAMS OF NURSING BY SCHOOL YEAR [1]

Discipline	School year				
	1973–77	1977–78	1978–79	1979–80	1980–81
Total	.....	77	200	[3] 270	[3] 270
Baccalaureate nursing	.....	40	160	180	180
Nurse practitioner [2]	.....	16	18	42	42
Nurse midwife	.....	8	12	19	19
Community health nursing	.....	13	10	29	29

[1] Awards were not available to nursing students until 1977–78.
[2] Nurse practitioner, nurse midwifery and community health nursing awards were available for applicants completing master's degree programs.
[3] Represent anticipated number of awards.

REQUEST TO OMB VERSUS PRESIDENT'S BUDGET

Senator BURDICK. Yes. Very good.

How did your original request to OMB for 1980 compare to the final 1980 President's budget for all your training programs? If you are having difficulty, you can put that in the record, too.

Dr. FOLEY. On every item, we could spend about 20 minutes to go through it. I would rather submit it to the record.

Senator BURDICK. You may.

Dr. FOLEY. We have it broken down by what the Bureau asked for, what HRA asked for, what the Public Health Service requested, what the Department requested, and what OMB basically accepted.

We will be glad to supply it for the record.

[The information follows:]

BUREAU OF HEALTH MANPOWER 1980 BUDGET HISTORY TABLE

[In thousands of dollars]

	BHM allowance	HRA allowance	PHS allowance	DHEW allowance	President's budget
Health professions:					
Institutional assistance:					
Capitation	65,800	66,833	41,287	5,900	.....
MOD	(56,600)	(57,633)	(35,387)	.....	.....
VOPP	(3,000)	(3,000)	.....	.....	.....
PH	(6,200)	(6,200)	(5,900)	(5,900)	.....
Financial distress	25,000	22,467	15,000	2,000	5,000
Startup	1,100	1,100	1,100	1,100	.....
Student assistance:					
NHSC	105,000	90,000	90,000	81,959	79,500
Loans	.....	.....	.....	.....	.....
Loan repayments	5,200	5,200	5,200	5,200	.....
Exceptional need school	10,000	10,000	10,000	5,000	.....

BUREAU OF HEALTH MANPOWER 1980 BUDGET HISTORY TABLE—Continued

[In thousands of dollars]

	BHM allowance	HRA allowance	PHS allowance	DHEW allowance	President's budget
Subtotal	212,100	195,600	162,587	101,159	84,500
Dental health education:					
TEAM Grants	5,000	3,000	5,000	2,000	2,000
EFDA	2,000	3,500	3,500	2,000	2,000
Educational development and application.	1,500	.....	.....	.....	.....
Subtotal	8,500	6,500	8,500	4,000	4,000
Public health:					
Special projects and public health and health administration	6,000	6,000	6,000	7,400	5,000
Graduate progress—Health administration	3,750	3,000	3,000	1,500	3,000
Public health traineeships	9,000	7,000	7,000	4,100	7,000
Health administration traineeships	2,500	1,500	1,500	1,000	2,000
Subtotal	21,250	17,500	17,500	14,000	17,000
Allied health:					
Special projects	26,000	16,500	14,000	1,410	.....
Traineeships	4,000	3,000	3,000	.....	.....
Subtotal	30,000	19,500	17,000	1,410	.....
Special educational programs:					
Family medicine/General dental	59,000	50,000	50,000	50,000	40,500
Medicine	(52,500)	(45,000)	(45,000)	(45,000)	(40,500)
Dentistry	(6,500)	(5,000)	(5,000)	(5,000)	.....
Family medicine departments	.....	.....	15,000	15,000	15,000
Primary care residencies	25,000	25,000	25,000	24,930	25,000
Primary care special projects	.....	.....	.....	7,889	6,000
Interdisciplinary training curriculum development	24,000	13,000	6,000	.....	.....
Physicians extenders	11,000	11,000	11,000	9,100	9,100
AHEC	19,000	19,000	19,000	19,105	5,825
Foreign medical transfers	1,000	1,000	1,000	1,000	.....
Emergency medical training	6,000	.....	.....	.....	.....
GMENAC	2,000	2,000	1,000	1,000	1,000
Manpower supply and distribution reports	15,000	15,000	10,000	5,900	5,400
Subtotal	162,000	136,000	138,000	133,924	107,825
Disadvantaged assistance:					
Health professions	20,000	20,000	20,000	20,882	18,068
Allied health	1,000	1,000	1,000	1,000	1,000
Subtotal	21,000	21,000	21,000	21,882	19,068
Nursing:					
Institutional assistance:					
Capitation	30,000	.....	.....	.....	.....
Advanced nurse training	12,000	15,300	10,000	.....	.....
Nurse practitioner	18,000	25,000	15,500	13,000	13,000
Special projects	20,000	7,500	7,500	7,500	1,743
Student assistance:					
Loans	.....	.....	.....	.....	.....

BUREAU OF HEALTH MANPOWER 1980 BUDGET HISTORY TABLE—Continued

[In thousands of dollars]

	BHM allowance	HRA allowance	PHS allowance	DHEW allowance	President's budget
Scholarships	.....	.....	.....	.....	.....
Traineeships	15,000	13,000	8,000	.....	.....
Loan repayments	.....	.....	.....	.....	.....
Fellowships	2,000	1,500	1,000	.....	.....
Educational assistance research grants	8,000	.....	.....	.....	.....
Subtotal, nursing	105,000	62,300	42,000	20,500	14,743
Total health manpower	559,850	458,400	396,587	296,875	247,136
Health teaching facilities:					
H.P. construction grants	.....	.....	.....	.....	.....
Nurse construction grants	11,000	.....	.....	.....	.....
H.P. interest subsidies	5,000	5,000	4,300	4,300	4,300
Total	16,000	5,000	4,300	4,300	4,300

1979 RESCISSION REQUEST

Senator BURDICK. Is your current 1979 request for substantial rescission a result of OMB recommendations?

Dr. FOLEY. Not just OMB. It was the considered opinion of many within the Department and within the agency that areas such as capitation in both the MOD and in nursing should certainly be reconsidered. We had testified last year not to support nurse capitation. We had testified to a lower number for the MOD, and we remained consistent with that. So, I could not and would not lay it totally on OMB. We were part of that decisionmaking process. There were differences in other line items, but not in those particular areas.

Senator BURDICK. Is it fair to say that they contributed somewhat?

Dr. FOLEY. They contributed, and we contributed, Senator.

Senator BURDICK. Dr. Foley, in your professional judgment are the strategies reflected in the current budget requests well-founded, or do you think the Health Resources Administration should be moving in other directions?

Dr. FOLEY. The strategies around capitation are well-founded. And as a professional, I can testify to those.

I think that there are areas that we will propose, both in relationship to nursing and the other health professions, by August of this year, which would recommend moving in new directions, building on the strengths that Congress has already built into law, such as the National Health Service Corps, primary care, family medicine, special project areas in nursing. And we would like to continue to basically use that as a creative thrust.

I will come back to you in the summer, after discussion with the professional groups as well as inside the administration, but I can say that part of this we definitely felt was consistent with that approach; no question.

EFFECTIVENESS OF HEALTH PLANNING AGENCIES

Senator BURDICK. Your agency has spent the past 4 years helping to establish a nationwide network of health system agencies, known as HSA's, and State health planning development agencies, SHPDA's, which are responsible for health planning and resource development for their areas.

How effectively can you realistically expect the HSA's and the SHPDA's to be? I wonder how often the HSA is going to be standing up in the area of local pressures from bankers, contractors, doctors, unions for the creation of new medical facilities regardless of actual area need? With regard to building facilities, persuasion is the only tool that HSA's have to have a facility closed or converted.

Will you be advocating an addition of decertification authority for HSA's under the legislation this year?

That is a long one. Can you handle it?

Dr. FOLEY. I think so, Senator. [Laughter.]

Now that we have moved from manpower, I am relieved to handle it.

Senator BURDICK. Well, I might have had one more question. [Laughter.]

Dr. FOLEY. I should refer to person power or health professions itself. Let me address the question.

We have seen in this past 3 to 4 years the basic establishment process of the health systems agencies in the country and the State health planning agencies. As I think Members of Congress are aware, in those cases where we felt that they were not doing a good job and it was a waste of the taxpayers' money, we, in fact, have not funded certain agencies. Los Angeles is one place where we are now working to establish an agency that will work for the population in that area.

As we have gone through this period of establishment, there has been a lot of discussion about process and now we are down to what, in fact, are the Health Systems Agencies accomplishing and the State agencies as well.

We have with the American Health Planning Association been involved in trying to find out from specific HSA's in the country and SHPDA's what they have accomplished.

We have seen in the past 2 years at the HSA level, the Health Systems Agencies in the communities, both consumers and providers, turn down $1.8 billion in applications both for modernization and construction of hospitals, as well as nursing home construction and modernization. This is consistent with the cost containment or the cost control aspect of the bill.

We have also seen instances where HSA's have helped to organize and coordinate services. For example, in your own State, the HSA and the State health planning agency have worked to merge several of the hospitals there and to make sure that physicians could get privileges in St. Luke's and prevent a duplication of equipment. As I recall it, the issue was around the CAT scanner question in that area.

We have also seen States begin to take a firmer position vis-a-vis cost controls, such States as New York and Massachusetts.

We think that there are others that need to increase their ability to control the costs. And we are now notifying the governors of those States to be sure that they have acceptable certificate of need laws required by statute.

We would find in this coming year, I think, probably less applications coming in for construction and modernization because many of the provider groups are recognizing that there is a tighter process in the health systems agencies.

That is in terms of cost containment. I think we have a question of access which is clearly defined under the law.

We have seen in some of the HSA's in this country the development of emergency medical services for populations, for example, in the San Antonio panhandle area. We have seen them getting together to develop and make sure that there are pediatric services, maternal and child health services, such as in St. Paul.

We are now in a position of evaluating each of the health systems agencies and State health planning agencies to come back to Congress with a detailed list which describes successes in the HSA's and States as well as areas we think need to be improved upon.

We are more than optimistic. We are aware that in some HSA's in this country, provider interests have dominated and we are continuing to work with the consumers in the country who are paying the bills, the taxpayer through public insurance or any of us through our private insurance.

We are concerned about the high cost of care that we are paying for, and we believe that that consumer element needs to be reinforced.

We have recently, through Dr. Rorrie, directed the Health Systems Agencies to dedicate one full staff person to the consumers on the Health Systems Agency boards so that they can have a more informed background as they try to deal with the provider interests that appropriately come in well prepared.

Providers have staff that they pay for to be sure that they can present good plans to the Health Systems Agencies and the SHPDA's.

We think that means that the consumers need a little bit more background to be able to deal in a fair situation.

As the Health Systems Agencies at the local level try to balance the concerns between cost control and access, our major concern is that we see more consistent action between the State agencies which have the real regulatory authority, and the local health planning agencies.

We had this past year a situation in one State where HSA's in various parts of the State had both providers and consumers turning down applications in areas that were overbedded by the State's own plan.

The State, however, was consistently overturning the HSA's.

We think there is a question of proper performance of that State's health planning agencies. We have notified the Governor to improve their performance and we would be prepared to defund if the performance did not improve.

We can't have the situation where States identify their own overbedding problems or access problems and then ignore them in their own activities.

We think that we are getting a better investment than we did 2 years ago because we are past the formative stages and I think we are going to see much better results over the next couple of years.

DECERTIFICATION

Senator BURDICK. You have skated close to my last question.

Dr. FOLEY. The decertification. We are recommending that in the administration's bill to extend Public Law 93-641, States that want to take the option to decertify would have the opportunity to seek Federal funds.

FULL DESIGNATION PROBLEMS

Senator BURDICK. Most of the Health Systems Agencies have either received full designation, or close to it. Yet, the State agencies, which are responsible for implementing the State health plans, are lagging far behind.

How many State health plans in development agencies, SHPDA's, will be fully designated within the next year? That is No. 1.

The certification of need feature appears to be the main stumbling block holding up full designation of most SHPDA's. Is this primarily a technical problem centered around State administrative practice, or regulatory interpretation, or are there real political questions in the States over this issue?

Dr. FOLEY. It is twofold: We will have 41 of the State agencies fully designated by the end of this calendar year. We do recognize that there are major political and substantive issues at the State level around the certificate of need law.

State legislatures spend enormous political energies trying to pass legislation which, historically, goes against the interest of much of the provider community. They are subjected to much lobbying to prevent that happening, much as the Senate and the House is subjected here when we discuss cost containment.

There has been resistance within State legislatures. We are now identifying to each State that doesn't have an acceptable certificate of need what its specific problem is. If they don't have a certificate of need, they need to pass one that is acceptable. If they have one on the books that doesn't meet the Federal statute, we are working with them in a technical assistance way to try to improve that.

We are talking about a very strong vested interest, clearly, and therefore, it results in a great deal of political action and infighting in State legislatures, and within the governorships of various States.

It is a difficult problem, but we think it is in the States' interest and we have recognized that some governors have taken some leadership in this area, particularly the Governor of Rhode Island; they recognize that with large medicaid programs, they also have an interest. With the incipient rate control commissions in some States, looking third-party reimbursement, there is tremendous pressure on governors and State legislatures to deal with the cost question.

That would hopefully help move to acceptable certificate of need program at State level.

Senator BURDICK. You say you have 41 State agencies established?

Dr. FOLEY. We will have 41 at the end of the year fully designated, Senator.

BUREAU OF HEALTH FACILITIES FINANCING

Senator BURDICK. At what stage in its development is the new Bureau of Health Facilities Financing?

Please explain to the committee how the new compliance and conversion program will work to contain the hospital costs.

How does the new bureau intend to encourage the Federal requirements that facilities would receive Federal funding providing health care to people unable to pay?

This was stated as one of the immediate goals of the bureaus in the agency's justification. What is the status of the proposed legislation for this program?

Dr. FOLEY. Senator, as I'm sure you are aware, we created that bureau by splitting what had been existing as the Bureau of Health Planning and Resources Development. We did so using existing positions to focus the activity of that staff, approximately 86 staff persons, on the areas of the assurances for both financial feasibility of the 3½ billion dollars' worth of loans that the Federal Government is guaranteeing under the HUD program, as well as the Hill-Burton program.

Second, it also has to monitor the assurances for free care and community service that is reflected in your question.

We have, at the present time, gone through the process of being formally sure and being sure bureaucratically that the job positions are adequately described in terms of civil service requirements.

There is staff working on the free care assurances. The regulations have been out as a notice of proposed rulemaking and will come out in final form by April. The staff at the regional level and at the central office are responsible for processing the complaints around the free care assurances. These complaints can be like what we saw on national news not too long ago about the young Chicano family, where the child was denied care in a hospital that had basically received Hill-Burton funds and had a free care insurance responsibility.

That patient was turned away, and in fact, died on the road in one of the Southern States.

We are involved in those situations to insure that, that does not continue, that that kind of behavior is corrected.

At the same time, we have, through monitoring the regional offices, a tracking system now developed on the loans themselves, to be sure that they are remaining financially feasible or viable, and that will continue.

That leads us now to the third area, which is the closure and conversion program area.

We are recommending in the legislation that it be an experimental program demonstration and that we get experience very carefully in the proposals we would look at to ensure we would be

funding those programs, those hospitals that would convert if they had funding to do so.

I was in the middle of Washington State. There are three hospitals up there in the tri-city area. And in that particular area, one of the hospitals could, in fact, close if there were a way for them to work out a retirement of their debt situation and amalgamate with the two other hospitals.

There was a willingness on the part of the board of trustees to do that, but there was no way they had a fiscal incentive to do it at the present time.

In fact, the way the rate control commission works in that State, it could keep that hospital financially viable just barely operating in the black, or a little bit in the red, and it would never close.

We think those types of facilities would be eligible for funding. We would look carefully at them and we would report back to both this committee and the authorization committee in the first year for oversight to see how successful we are doing in that program.

That is the $30 million request that is in the appropriation here.

SAVINGS AS A RESULT OF CONVERSION AND CLOSURE

Senator BURDICK. How much money do you expect to save as a result of the $30 million investment?

Dr. FOLEY. That is primarily why we are calling it experimental or demonstration. I think if one has tried to merge or close hospitals, one finds that that process takes a couple of years, and that one might not realize savings in the first year. Maybe in the second or even the third year.

So I would be reluctant at this point to say what in the first year would be our savings. I think over the lifetime of the $30 million, we are estimating that we would be able to reduce the number of beds anywhere from 1,000 to 1,500 beds, and therefore save, in terms of both the fixed costs for having those beds as well as the operating cost for those beds as well.

Senator BURDICK. I have 50 or 60 more questions here. [Laughter.]

Some dealing with capitation, nursing schools and so forth, and other subjects.

Dr. FOLEY. I was going to say in the House, there were 10 Members coming at me. In here, it would be only yourself and I think both of us would be exhausted.

Senator BURDICK. And I can be 10 times as intense, too.

We will submit these for the record, and we would be glad to have your replies.

Dr. FOLEY. I would be glad to respond.

QUESTIONS SUBMITTED FOR RESPONSES

Senator BURDICK. We have several questions for the record. There are also a few statements from nursing groups which will be placed in the record, which will be received, without objection at this time.

[The information follows:]

HEALTH PROFESSIONS STUDENT LOAN (HPSL)
ANNUAL INTEREST RATE - 7% SIMPLE

Amount of Total Debt	MONTHLY PAYMENTS In School (Interest)	During Repayment (120 Months) (Principal & Interest)	Ten Year Period Total Repayment Amount (Principal & Interest)
$ 5,000	None	$ 58	$ 6,415
10,000	None	116	12,830
15,000	None	174	19,244
20,000	None	232	25,659
25,000	None	291	32,074
30,000	None	349	38,489
35,000	None	407	44,903
40,000	None	465	51,318
45,000	None	523	57,733
50,000	None	581	64,148

Under the Health Professions Student Loan Program, interest is not compounded. No interest is charged while the individual is in school nor while the individual is in deferment for periods of advanced professional training, active duty in the uniformed services, or service in the Peace Corps.

The projected average annual loan for FY-80 is $9,500. The average monthly repayment amount for a one-year loan is $110.39 with a total finance charge of $2,688.03 over a maximum 120 months repayment period for a total repayment amount of $12,188.03.

THE HEALTH EDUCATION ASSISTANCE LOAN PROGRAM (HEAL)

Amount of Total Debt	Monthly Payments In School (interest)	During Repayment (120 Months) (Principal & Interest)	Ten Year Period Total Repayment Amount* (Principal & Interest)
$ 5,000	$ 50	$ 72	$ 8,640
10,000	100	143	17,160
15,000	150	215	25,800
20,000	200	287	34,440
25,000	250	359	43,080
30,000	300	430	51,600
35,000	350	502	60,240
40,000	400	574	68,880
45,000	450	646	77,520
50,000	500	717	86,040

This table presents the repayment obligations on outstanding loans in varying amounts at the maximum ANNUAL PERCENTAGE RATE (APR) of 12% for the minimum repayment period of 120 months. Monthly payments will be less if the Annual Percentage Rate is less than 12%. Since various options are available to the lender in determining the actual rate and method of interest payment, the borrower should have a clear understanding of the responsibilities incurred. At the option of the lender, a borrower may defer interest payments prior to the repayment period. If this is done, however, this interest may be compounded every six months and added to the principle amount borrowed. This will add significantly to the monthly payment during the repayment period.

* This total amount does not include interest charges which the individual incurs during his time in school or in deferment status.

QUESTIONS SUBMITTED FOR RESPONSES

Senator BURDICK. We will have all responses to the questions. Can you have them in 7 days?

Dr. FOLEY. Yes.

[The following questions were not asked at the hearing, but were submitted to the Department for response subsequent to the hearing:]

REGIONAL CENTERS FOR HEALTH PLANNING

Question: What kind of assistance is provided by these 10 Regional Centers for Health Planning that couldn't just as well be provided by HEW's Regional Offices?

Answer: The ten regional centers have had the central role in providing two basic kinds of assistance to health planning agencies' staffs. Some of it is on the order of on the job training and some continuing education.

The Centers provide this assistance through training sessions, consultations, productions of generic documents on specific topics and information about and referral to the literature.

To agency boards and Statewide Health Coordinating Councils (SHCCs) they mainly provide training in matters that deal with consumer and provider input into the decision-making processes. Agency board and SHCC volunteers have also participated in other training provided to staff.

To give you an example, during the last three months 44 major training courses were offered by the ten Centers to their clients on such diverse topics as Basic Training of New Staff, Criteria and Standards: Making review decisions, Conference for Data Managers, Multi-hospital Arrangements, and Hospital and Long-Term Care Facility Capital Expenditure Analysis.

The regional offices' role in providing technical assistance of this kind has been minimal. Their role has been to assist the agencies through monitoring the progress of the agencies and ensuring compliance with the Federal expectations.

Question: Isn't this just another opportunity for duplication of effort?

Answer: The Centers have about ten staff members per region devoted to the technical assistance effort, while the regional offices average less than one. Technical assistance provided by the Centers could not be duplicated by the regional offices either in numbers of staff or types of services offered or in scope.

CONSOLIDATION OF HEALTH PLANNING CENTERS

Question: Please explain to the Committee why you are consolidating your 10 health planning centers into 4?

Answer: The move from ten to four Centers is an effort to do several things, namely, to strengthen the program and reduce some inefficiencies; to limit the areas in which technical assistance can be provided to the three principal tasks of plan development, data management and analysis, and plan implementation including project review; to ensure better management of the program, reduce duplication of effort and increase the sharing of information; to ensure comparable performance by all Centers; and to provide the agencies with continued technical assistance while we phase in a more streamlined Federal effort directly by our own staff.

We have now embarked on a process of assessing the ten Centers to learn how they have done in the past and how we can help the agencies. That study will be completed in May and will be used as input into the design of the four Center approach.

Question: How much money is this consolidation expected to save?

Answer: The amount of savings will be minimal and attributed to a decrease in overhead costs. The four Centers will continue to cover the nation, each serving a larger geographic area of the country.

REPORTING SYSTEM

Question: Has an effective reporting system been established as required by the 1974 Health Planning Act to measure the performance of planning agencies?

Answer: Certain components of the health systems agencies' (HSA) reporting system have been established and include the HSA Annual Baseline Report, the HSA compliance performance standards and State Health Planning and Development Agency optimal performance standards. The agency self-assessment system -- an evaluative tool -- is currently being tested, and the HSA quarterly report on agency progress will be revised in April. The HSA optimal performance standards and the SHPDA compliance performance standards are currently under development.

Question: Does the reporting system include a method of obtaining information on the number and types of MDs on health planning boards?

Answer: The HSA Annual Baseline Report approved by OMB does not contain a mechanism for obtaining information on the number and types of physicians on the health systems agencies' governing bodies.

Question: I understand you were having some problems in developing a method which would be acceptable to OMB.

Answer: We have had and continue to have discussions with OMB to come up with the information we require without placing undue reporting burdens on the planning agencies. At OMB's request we provided an assurances checklist and a consumer profile indicating age, sex, race, language and income which OMB approved and indicated should suffice for information we should need. The checklist did not include any information on providers other than information which assured compliance with statutory requirements.

PER-CAPITA FUNDING OF HEALTH SYSTEMS AGENCIES (HSAs)

Question: It seems that small, rural HSAs -- like Eastern Washington HSA in Spokane -- tend to be underfunded with the $0.44 - $0.46 per capita funding made available by DHEW. What is being done to remedy this situation?

Answer: We have proposed changes to the enabling legislation which would provide the Secretary with full discretion for funding of HSAs. Should the legislation containing that provision become law, we intend to take action which would better provide for minimally funded agencies. An additional planned course of action is to reexamine the funding formula and revise it to provide for a more appropriate and equitable method of distributing available funds to all HSAs.

Question: What ever happened to the $0.75 per capita funding level originally proposed in P.L. 93-641?

Answer: The $0.75 per capita contained in P.L. 93-641 assumed a maximum of $0.50 per capita for population and a maximum of $0.25 per capita in Federal matching funds for eligible local contributions. While the per capita for population will be approximately $0.46 in 1980, the amount of local contributions will fall far short of the $0.25 entitlement. In order to receive the full $0.25 per capita matching, agencies would have to raise approximately $55 million in eligible non-Federal contributions as contrasted to the $11.0 million they are expected to raise in 1980.

1979 FUNDING LEVEL

Question: The 95th Congress failed to enact the legislation which would have made some significant changes in the existing health planning program. How will the planning agencies be affected by this and by the need for a further reconsideration in the 96th Congress?

Answer: The greatest impact on the planning agencies by the failure of the 95th Congress to enact the proposed health planning legislation is in the area of resource allocation.

Some agencies are continuing to operate at a minimal level of funding and are suffering from an inability to maintain the level of professional staff necessary to retain their full designation status. Some agencies have terminated positions, curtailed staff travel and training, and, in some cases, converted to a four-day work week. As the rate of national inflation continues to rise, these negative effects will be compounded.

While the Administration's proposal does not specifically address the problems of minimally funded health systems agencies (HSAs), a change is proposed which would give us the flexibility to reassess the minimally funded HSA problem and act accordingly. That change would allow the amount of a grant to an HSA to be determined by the Secretary. If accepted, it would enable us to better deal with the problems of all HSAs and specifically those which are minimally funded.

Recognizing that there are divergent views about what is considered to be an adequate minimum funding level, and because of the need for periodic reassessment due to changing circumstances, we conconsider it wiser that there be a degree of flexibility rather than a fixed minimum funding level for all HSAs.

It is imperative that the 96th Congress reconsider and enact this proposed legislation so that the HSAs can begin to sufficiently operate at full performance levels.

Question: Since the program has been extended for FY 1979 at the FY 1978 levels, doesn't this actually represent a reduction of effort?

Answer: The inflation factor will in itself diminish the degree to which agencies can perform at same level funding. Moreover, 1979 represents the first full year in which most health systems agencies will be operating under full designation and, as such, assume additional and greater responsibilities. Coupled together, these factors will necessitate a reduced or modified level of effort by the agencies.

Question: Which agencies will be hardest hit by these funding levels?

Answer: The minimally funded agencies will continue to be hard hit due to the fact that they must absorb the same types of basic costs as the larger agencies, such as overhead costs. Some of the larger agencies are experiencing financial problems with such things as legal costs. If our legislative proposal for discretionary funding is enacted, most problems such as these could be substantially reduced.

NATIONWIDE CAPITAL EXPENDITURE LIMIT

Question: What will be the nationwide capital expenditure limit that the Bureau of Health Planning will be working with in 1980?

Answer: The amount of capital expenditure limit for 1979 for short-term hospitals is $3 billion. This amount would be adjusted for inflation of construction prices in 1980.

Question: What is the basis for this expenditure limit?

Answer: Previous levels of hospital capital expenditures are in the range of $5-6 billion. The Department of Commerce preliminary estimate for 1978 of hospital construction completed was $5.1 billion. Thus setting the capital expenditure limit at $3 billion would provide for a reduction of somewhat more than one-third in the level of capital expenditures.

Question: Is the hospital industry satisfied with this goal or do they generally support a higher limit?

Answer: Different parts of the hospital industry have different opinions. There seems to be general support for the idea of limiting capital expenditures. There are varying estimates of where to set that limit. The National Council of Community Hospitals has gone as far as to suggest a two-year moratorium on almost all capital expenditures. Other hospital groups in the past have worked in the legislative process toward a capital expenditure limit of $4 billion or higher.

CERTIFICATE OF NEED

Question: How many States are not in compliance with Federal certificate of need requirements and how extensive are these deficiencies?

Answer: Forty-two States have not yet met minimum Federal certificate of need requirements for full State Health Planning and Development Agency (SHPDA) designation. Additionally, six territories and the District of Columbia do not have programs which are satisfactory to the Secretary of Health, Education, and Welfare. The deficiencies in these States and territories vary widely.
Nine States and two territories have not yet enacted certificate of need legislation. Of those States that do have statutes, some will require legislative amendments in order to meet minimum Federal requirement for a satisfactory program. Other States do not require statutory changes, but will need revisions, additions, or clarifications to regulations before the program will be found to be satisfactory to the Secretary. In several States, officials are making efforts to adopt a certificate of need program that conforms to the provisions of the Planning Act. Other States, though, have shown varying degrees of resistance to certificate of need, and seem reluctant to adopt a satisfactory program before conditional SHPDA designation expires.

Question: What steps are being taken to reduce the number and scope of these deficiencies?

Answer: The Central Office has been working very closely with regional office staff to help secure full designation agreements in as many States as possible. The regional offices, in turn, are working with the legislature, the Governors office, and the SHPDAs in each State. Finally, the Department will contact the Governors of all States not having acceptable certificate of need programs in order to advise them on the status of their program and offer further regional and central office assistance.

It is important to emphasize that what is required of SHPDAs is that they have the authority to administer a satisfactory certificate of need program. The SHPDA must secure whatever combination of authorities -- statutory, regulatory, assurances by the Attorney General, and so forth -- that may be necessary to administer a program meeting minimum Federal requirements.

Question: Does the 1980 budget contain sufficient resources to bring all States into complaince with certificate of need requirements?

Answer: The 1980 budget allows us sufficient resources to support State efforts to meet certificate of need requirements. However, compliance with certificate of need requirements is not so much a funding issue as it is a political issue at the individual State level.

ORGANIZATIONAL PROBLEMS

Question: Have organizational problems in the Bureau of Health Planning been resolved?

Answer: Substantial progress has been made in alleviating some of the long standing organizational problems in the Bureau of Health Planning, particularly those referred to in the GAO report. The recent reorganization of the Health Resources Administration has restructured the agency into three Bureaus, the Bureau of Health Manpower, the Bureau of Health Planning and the Bureau of Health Facilities Financing, Compliance, and Conversion. By splitting the old Bureau of Health Planning and Resources Development into two new Bureaus, the Agency will be in a position to more effectively implement the programmatic requirements of the health planning act. For example, within the immediate office of the Director specific staff have been assigned responsibility to coordinate the Bureau's activities with the HEW Regional Offices in an attempt to improve communications with the Regions and to more consistently implement National policy.

INTERNAL PROBLEMS WITHIN THE PLANNING BUREAU

Question: The resignation last spring of Dr. Harry Cain as head of the Planning Bureau received quite a bit of attention. Has that bureaucratic swamp that Dr. Cain referred to been drained yet?

Answer: The problems referred to by Dr. Cain are largely reflective of a large complex organization, the Federal Bureaucracy, and may be compounded by the wide-ranging and detailed issues posed by the health planning process. Within HRA, we are concentrating on developing our capacity to resolve these issues.

But there is no doubt that the red tape that largely stimulated Dr. Cain's departure is still very much with us.

Question: Dr. Rorrie (his successor), what's your perspective on the kinds of problems Dr. Cain was referring to?

Answer: My own personal perspective is that while some progress is being made to address the basic problems, the problem of red tape will always be with us. My overriding concern is that this red tape not keep us from getting the job done in the field.

Question: Will you comment candidly as to whether morale at the Planning Bureau is still a problem?

Answer: Some improvements in staff morale within the Bureau have been made over the past six months as a result of the Agency reorganization and appointments of key staff within the Bureau. However, some morale problems do remain and are traceable to a number of factors. First the uncertainty of whether and when our legislation will be extended affects the ability of staff to move forward aggressively in continuing to implement the requirements of the Act. Secondly, there remain substantial personnel concerns which have an impact on staff morale. Specifically, the issue centers around senior staff who have been detailed to lower graded jobs because of an inability to place them in jobs at their grade level, in conjunction with other lower graded personnel who see limited opportunities to advance within the Bureau because they believe their advancement is blocked by the larger numbers of senior staff.

ENERGY

Question: Last year you mentioned your Agency's efforts to encourage and train Administrators and Staff of Health Care Facilities to conserve energy and use it more effectively. Have these efforts been initiated? If so, have any cost-saving results been realized?

Answer: In 1977, HRA presented nine regional and State energy management conferences. These conferences were attended by health institution administrators, department heads and plant operating personnel, as well as State and local health planning and licensing staff. In addition, the HRA Energy Staff made presentations at nineteen national and local health professional meetings.

In 1978, HRA's Energy Staff developed seven State and local energy management conferences which were sponsored by local health and energy organizations. They also appeared as key speakers at these and five other energy conferences. The Energy Office also assisted the American Hospital Association (AHA) in obtaining outside funding to initiate an energy conservation program in the nation's hospitals, and provided the AHA and other organizations in establishing energy conservation awards and conservation programs for their constituencies.

As a result of these and other technical assistance and information activities, it is estimated that energy management savings in hospitals are at least five percent or about $165 million annually at today's energy costs.

These energy savings are projected to increase. The energy management conferences provided the mechanism for the identification of local hospital and nursing home personnel who have effective energy management experience. Therefore, these individuals can serve as a counseling resource for expanded conservation activities in the health sector. Additionally, the conferences introduced health professionals to the energy management manuals "TOTAL ENERGY MANAGEMENT FOR NURSING HOMES".

In 1978, a special energy/health Issues Discussion was convened by HRA to provide a coordinated look at energy related issues in the health sector. Participants included representatives from American Hospital Association, American Medical Association, American Association of Medical Colleges, Association of Hospital Financial Management Officers, Blue Cross Association, Department of Defense, Department of Energy (DOE), Veterans Association, and others. A Collateral effort has been the commissioning of a number of health/energy issues papers, which are presently being prepared for dissemination.

HRA has administered the DOE solar energy demonstration program in the health sector since 1977 and will have about 15 demonstration projects in place in 1979.

DEPARTMENT OF HEALTH EDUCATION AND WELFARE HEALTH MANPOWER POLICY

Question: Has the Department of Health, Education, and Welfare developed a specific Federal health manpower policy? Explain.

Answer: In recent months the Department has been making an intensive review of its health manpower programs with particular attention to the need for developing a clear policy on the Federal role in assuring an adequate number of the right types of health professions personnel to provide health care for the people of the United States. Various groups within the Department have participated in this review. A clear manpower policy is needed as a basis for preparing legislative proposals as well as for budget planning purposes. The Department expects to submit a legislative proposal to the Congress later this year.

Question: The Health Professions Educational Assistance Act of 1976 expires at the end of fiscal 1980. What direction will new legislative proposals take? Describe any changes HEW would like to make in current programs, and the subsequent impact on the budget. What are the major problems such legislation must attempt to solve?

Answer: Since the Department is still working on its health manpower legislative proposal for fiscal year 1981 and beyond, we cannot at this time list specific changes in law that will be sought. However, the general outlines of the proposal are taking shape. In his speech to the Association of American Medical Colleges last October, the Secretary stated that the first tenet of national policy in the health professions area is that overall we face in the next decade an oversupply of physicians. Second, we are producing too many medical specialists and subspecialists at the same time that there is a decline in the proportion of primary care physicians. The third tenet of national policy is that the physicians we do have are seriously maldistributed in geographical terms. Fourth, medical schools must take a more active role in making physicians responsive to demographic, social, and economic changes which have deep implications for health care.

GEOGRAPHIC AND SPECIALTY MALDISTRIBUTION

Question: Is any progress being made toward alleviating the problem of geographic and specialty distribution of health manpower?

Answer: There is some limited evidence that the geographic distribution situation has begun to stablize or perhaps even improve slightly, at least among physicians. The long-term trend toward loss of physicians and lower physician-population ratios in rural counties appears to have been reversed, and there appears to have seen some actual improvement since 1970. Furthermore, a recent American Medical Association analysis also indicated some improvement in the distribution of patient care physicians on a regional basis between 1968 and 1976. Primarily because of data problems, however, it is more difficult to determine with any degree of assurance the progress being made in improving the distribution of the other health professionals.

Question: How do you intend to use the resources you are requesting in 1980 to move closer to the solution of this problem?

Answer: The Nation's health manpower needs of today are those of improving geographic distribution, increasing the proportion of health professions students entering primary care specialties, raising the productivity of professional personnel, and improving health career opportunities for the disadvantaged. As reflected in the President's Budget request for fiscal year 1980, the Administration favors carefully targeted support of such programs as family medicine residency training, National Health Service Corps Scholarships for students who commit themselves to serve in shortage areas, primary care residencies in general internal medicine and pediatrics, development of sound health manpower data, and assistance to disadvantaged students. By directing our financial resources to these programs we can move closer to alleviating the problem of geographic and specialty maldistribution of health professionals in this country.

Question: Is HRA planning to initiate any new measures to improve the problem of geographic and specialty maldistribution?

Answer: Although HRA is not planning to initiate any new measures to improve geographic and specialty distribution under existing legislative authorities, it is working with others in the Department to develop a health manpower legislative proposal for fiscal years 1981 and beyond which will focus particularly on the need to overcome problems of maldistribution.

GEOGRAPHIC AND SPECIALTY MALDISTRIBUTION

Question: What is the most recent appraisal of the maldistribution problem?

Answer: Despite the significant increases in the aggregate supply of health professionals since the early sixties, geographic maldistribution remains a major concern. The Bureau of Health Manpower, in coordination with the Bureau of Community Health Services, has many programs which focus efforts on alleviating problems in areas which have been identified as health manpower shortage areas. During the past year, over 1,200 areas were identified as shortage areas for primary medical care manpower, and more than 600 as shortage areas for dental manpower.

As has been commonly observed, major geographic variations in physician/population ratios still exist. With respect to urban/rural (for instance, metropolitan/nonmetropolitan) differences, for example, 1976 figures show that there were 520 people per physician in metropolitan areas. The situation in nursing appears to be similar to that for physicians, at least as based on nurse/population ratios.

SPECIALTY SUPPLY SHORTAGE

Question: In the FY 1979 hearings, it was stated that supply shortages existed in such specialties as large animal veterinaries, clinical pharmacists, nurses with advanced degrees, medical record administrators, and physical therapists.

What has HRA done to help alleviate this problem?

Answer: With respect to medical record administrators, physical therapists, dietitians, and other allied health specialists for which supply or distribution may be a problem, Health Resources Administration has continued to utilize allied health institutional support and advanced traineeship funds to maintain educational programs and increase faculty. In connection with a forthcoming report to the Congress on allied health manpower, we are re-evaluating the situation in these specialties. The Military Experience Directed Into Health Careers program, originally for placement of veterans, has in nine States expanded to assist institutions and communities in filling critical vacancies with non-veterans as well. During fiscal year 1979 we hope to increase this to twelve States, and have earmarked $1.2 million for the Military Experience Directed Into Health Careers program this year. We are encouraging and supporting regional and State health manpower planning both on the part of health planning agencies and by the major educational institutions which produce these individuals. Finally, but not least, we are improving our information base so that we can more accurately judge where manpower problems exist and how they can best be solved.

The Division of Nursing, Health Resources Administration, has supported some 84 programs related to the preparation of the nurse for clinical practice at the graduate level over the past three years. These programs, located throughout the Nation, have provided support to programs which have enrolled approximately 1,500 students.

Health Resources Administration has responded to the geographic shortages of large animal veterinarians through the $26 million construction program for regional schools of veterinary medicine in fiscal year 1977 and in the capitation programs by requiring an assurance of clinical training emphasizing predominately food producing and fibre producing animals. In fiscal year 1978, all 22 participating educational programs provided this assurance and were awarded a total of $5.379 million that will be available through September 30, 1980.

SPECIALTY SUPPLY SHORTAGE

Shortages of clinical pharmacists have been addressed by the capitation grant program in requesting an assurance for clinical training of pharmacy students in 4 specified clinical areas. These are: an inpatient and outpatient clerkship experience in a hospital, extended care facility, or other clinical setting--instruction with physicians and other health professionals--training in the counseling of patients with regard to the appropriate use of and reactions to drugs and--training in drug information retrieval and analysis in the context of actual problems. A total of $9.495 million was awarded in fiscal year 1978 and will be utilized through September 30, 1980. All schools are required to give this assurance in order to be eligible.

Question: How does the Administration's attempt to cut VOPP capitation grants affect this effort?

Answer: Since the Capitation program has shown considerable success by the successful enrollment expansion and the subsequent rise in graduates in the health professions, the improvement for the distribution of health professionals will directly be addressed by increasing the funding of the National Health Service Corps Scholarship program and other Primary Care programs.

Question: In the FY 1979 hearings, it was stated that maldistribution of dentists, optometrists, pharmacists and veterinarians "exists but is less marked." Has there been any improvement in this distribution situation?

Answer: Little change in the distribution situation can be clearly identified at this time, partially because of the long time period involved before health professionals recently or currently in training actually enter the workforce, and the long lead-time necessary to obtain the relevant data to evaluate small changes. Given the past intractability of distribution problems, the difficulties of measuring maldistribution, and the long lead-time required before professionals now in training can have an impact, it appears that even the strengthened shortage area programs in Public Law 94-484 may not be able to change the maldistribution situation significantly or quickly. However, in the specialty area, major increases in residents in family practice programs and primary care general internal medicine programs provide some indication that the medical specialty situation may be changing for the better.

MEDICALLY UNDERSERVED AREAS

Question: Currently, how many medically underserved areas are there in the country and what is the mix of urban versus rural areas?

Answer: According to our most recent figures on the health manpower shortage areas that are used for placement of National Health Service Corps personnel and for repayment of educational loans (among other programs), a total of 1,232 areas have been identified as primary medical care shortage areas as of the end of 1978. Of these 886 (72 percent) were in nonmetropolitan areas and (28 percent) were in metropolitan areas.

Question: What is the distribution of the total population residing in these areas--urban versus rural?

Answer: In the 1,232 primary care shortage areas designated as of the end of 1978, there was a total of 27 million persons. Of this number, 14 million (52 percent) lived in metropolitan areas, while 13 million (48 percent) lived in nonmetropolitan areas.

FUTURE REQUIREMENTS FOR HEALTH PROFESSIONALS

Question: Seeing as capitation grants helped increase health professions enrollments, thus assuring adequate supplies into at least the mid-1980's, what do you think will be the factors which will ensure that the health profession enrollments will not decrease and threaten the supply of health professions in the 1990's?

Answer: The capacity of health professions schools and the number of students currently in the pipeline are expected to provide adequate supplies of health manpower in 1990 and beyond. Although the ratio of applicants to available places in some professions had edged down somewhat, there are still more qualified applicants to these schools than can be accepted. It is expected that the favorable earnings of health professionals and the other attractions of these occupations will continue to attract large numbers of highly qualified applicants, and that the elimination of capitation will not have the effect of reducing school capacity appreciably, if at all, especially in the face of these high demands for admission. Even if small decreases in enrollments were to occur, they would not significantly or irrevocably effect the manpower supplies of the 1990's. In both our health manpower analysis and our evaluation programs, we plan to monitor very closely changes in enrollments and graduates and in total manpower supply, and to develop more precise supply and requirements forecasts. We intend to identify potential developments in our future manpower situation before they occur, and therefore to be able to develop new policies as they are appropriate and with the necessary lead time. For the present, the expectation is that aggregate national health manpower supply and requirements in the health professions will be in balance in the 1990's and, therefore, that resources should be directed to more critical needs.

Question: What has been done to bring uniformity to the analytical approaches which have provided contradictory findings on the requirements of health professionals for the country in the future?

Answer: No single approach to estimating requirements for health manpower has proved completely satisfactory or able to provide the myriad of information currently needed. Different approaches, therefore, are sometimes taken for different purposes and to meet different needs. For example, different methods are used to develop requirements estimates based on the "need" for health care and health manpower than are used to develop estimates based on economic demand and cost considerations or current utilization patterns. Perhaps even more significantly, long-range forecasts that must be based on possible human decisions in activities as complex and important as the delivery of health care will necessarily and naturally be subject to some uncertainty. As a result, requirements estimates and projections need to be continually developed, refined and evaluated.

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Despite these problems, however, substantial progress has been made in bringing more information and compatibility into our analytical activities. New and improved methods are well along in the development stage and detailed, formal evaluation of various physician, dental nursing, general care delivery, and other health manpower models are underway or being completed. Steps are also being taken to increase the uniformity of data, assumptions, and methods used, and to explain requirements estimates in a more detailed, comprehensive, and easily understood fashion. One important aspect of this effort has been the reorganization of the formerly dispersed and discrete analytical effort of Bureau of Health Manpower into a single Division of Manpower Analysis, which will help to improve the consistency of manpower analysis and will permit us to more effectively employ our resources for improving and expanding these efforts. We have placed a high priority on our manpower analysis program, with our objective being to continue improvement of our analysis, which is a vital component of more consistent and accurate forecasts of health manpower requirements.

GEOGRAPHIC AND SPECIALTY MALDISTRIBUTION

Question: In a report submitted by OMB to this committee, it was expressly stated that the President wanted Federal support to be targeted towards programs which address geographic and specialty maldistribution. But last year, of the programs mentioned to address the problem, the President did not even increase the programs to reflect the impact of inflation. Why?

Answer: Although the President's intent was to emphasize health manpower programs to address the geographic and specialty maldistribution problems, the limited resources that are available determined the extent in which he could allocate his resources in this important area. Even though the Administration did not increase all of the programs that impact on the geographic and specialty maldistribution problems, we did request an increase in funds in two key program areas - namely, the National Health Service Corps Scholarship and the Primary Care Residency and Training programs. The National Health Service Corps Scholarship program, which is the single most important funding mechanism to address these problems, is being increased to $79.5 million. Primary Care Residency and Training funding level will be increased to $25 million.

CAPITATION GRANTS FOR VETERINARY SCHOOLS

Question: OMB stated in a report to this Committee that capitation grants for veterinary schools would be phased out to reflect the lack of critical geographic or specialty shortages. However, in FY 1979 hearings it was stated that there currently is a shortage of large-animal veterinarians. Is there a significant shortage?

Answer: While the area of greatest veterinary need is for farm animal or large animal practitioners, it is not believed that there is a significant shortage nationally. Added needs for farm animal practitioners exist primarily in remote areas, where there may be insufficient economic demand for veterinarians to establish what is otherwise viewed as a much-needed practice.

Question: Is this situation very serious?

Answer: Anticipated increases in the supply of veterinarians, largely due to development of five new schools of veterinary medicine in recent years, will likely be the largest among all of the health professions. It is expected that a sizeable proportion of the large number of new veterinarians graduating in the coming years will, in fact, become farm animal or large animal practitioners. In addition, programs exist to train non-veterinarians to perform tasks relating to care of food animals formerly performed by veterinarians.

REGIONAL OPTOMETRIC AND PODIATRY SCHOOLS

Question: Has priority been given to a regional optometric school and regional podiatry school in the Midwest and a regional osteopathic school in New England?

Answer: Start-up Assistance grant applications were received for a proposed regional osteopathic school in New England and a regional optometric school in the Midwest. These schools were the New England College of Osteopathic Medicine and the University of Missouri/St. Louis School of Optometry. No application was received for a proposed school of podiatry in the Midwest.

Both applications were reviewed by a panel of consultants and the National Advisory Council on Health Professions Education. The New England College of Osteopathic Medicine's grant application was approved at the funding level requested for a 3-year period of eligibility. An award of $270,000 for the first year was made on February 2, 1979.

The grant application submitted by the University of Missouri/St. Louis School of Optometry failed to meet the statutory requirements relating to "other resources available to such school" as established by section 788(a)(1)(B) of Public Law 94-484 and was therefore recommended for disapproval for funding by both the review consultants panel and the National Advisory Council on Health Professions Education. The School also failed to submit evidence of reasonable assurance of accreditation as provided by section 772(b)(2)(A) of Public Law 94-484 and as specified in section 57.1402 of 42 CFR Part 57, Notice of Proposed Rulemaking. For these reasons, the application was disapproved for funding.

Question: How were the funds dispersed?

Answer: An amount of $270,000 for first year funding was made to the New England College of Osteopathic Medicine on February 2, 1979. Five other new grants, plus one supplemental and ten continuations were also awarded at this time.

HEALTH PROFESSIONS TRAINING

Question: The Administration has expressed a reluctance to subsidize health professions training with public funds in view of the fact that these professions will enjoy socially prestigious livelihoods and a relatively high annual income. Do you share this reluctance?

Answer: Yes, I share that reluctance; however, I recognize that only students that come from wealthy backgrounds could afford the full cost of this education. Therefore, our policy is to provide support though the National Health Service Corps Scholarship program where the recipient who has benefited from the use of tax dollars will be obligated to repay the American people in the form of service in shortage areas.

CAPITATION GRANTS

Question: The Committee has been under the impression, as witnessed by FY 1979 Report Language, that capitation grants is "a program designed to help schools to maintain or increase levels and to alter specialty and geographic distribution patterns". Do you believe that the Capitation Grant program has been helping to alleviate maldistribution problems?

Answer: Capitation funding, under previous legislation, was directed toward increasing enrollments. Analysis of this capitation program has shown it has been a success. More recently, federal concern has shifted from the problems of achieving aggregate numerical adequacy of manpower nationally to the problems of improving geographic and specialty distribution. The current capitation program does not impact directly on this problem. To qualify for capitation support medical schools must have specified percentages of filled first-year residency prositions in direct or affiliated residency training programs in primary care. The required percentage in 1980 is 50 percent. Since the goal for 1980 had been achieved prior to 1978, the program cannot be viewed as a significant tool for impacting on either specialty or geographic maldistribution problems, especially since many physicians adjust their specialties after their first year of training.

Question: Can capitation grants realistically be used to help alter specialty and geographic distribution patterns?

Answer: Capitation funds support undergraduate medical training. The most effective way to influence specialty choice is to influence graduate medical training. Other programs such as the National Health Service Corps Scholarship programs, Family Medicine and Primary Care Residencies and Training, Nurse Practitioner programs achieve national goals more effectively than capitation.

MINORITY SCHOOLS

Question: I want to express my continuing concern with the problems being experienced by minority medical schools. The Committee has recognized the special problems of Tuskegee, Xavier, and Meharry Medical College. Last year both the House Committee and the Senate Committee asked the Secretary of HEW to draft a report outlining the current financial status of these institutions. What is the status of that report, and when can we expect to receive it?

Answer: Because of the complexities of the financial problems of these schools and to assure a thorough analysis of their needs and their contributions, the report has been delayed. We plan to provide the report in April.

Question: The committee also directed that the report should outline proposed methods for meeting the immediate financial crisis and a long-term method for these institutions to achieve financial stability. For the record, please tell us what HEW is planning to recommend in this regard..

Answer: Because the Secretary has not had the opportunity to review the report and select an option, I cannot be specific on what our recommendations will be. However, considering the contribution of these schools, we will be seeking ways to continue their viability.

Question: Certainly there is general agreement that these schools should not become dependent on this funding. However, there is certain national need to provide trained minority personnel for the medical profession. These schools are in deep financial trouble and there is no alternative for the moment to providing continued financial distress funding. I am pleased that the Administration has recommended $5 million, the authorized level, for FY 1980. Please tell us how the $5 million is being distributed in FY 79 and how you propose to distribute it in FY 1980.

Answer: A grant cycle for FY 79 has been nearly completed and six awards have been made as follows:

	(in thousands)
Tuskegee Institute School of Veterinary Medicine	$ 116.2
Xavier University of Louisiana College of Pharmacy	129.5
Columbia University School of Dentistry and Oral Surgery	148.5

Massachusetts College of Pharmacy	218.5
Meharry Medical College	
School of Dentistry	927.9
School of Medicine	2,065.0
	$3,605.6

It is too soon to know how fiscal 1980 funds will be allocated.

Question: The Administration proposes to delete funding for capitation grants to medical schools. Please tell us how each of these minority institutions will be affected by the proposed reduction in capitation.

Answer: This would be a loss of general support funds to these schools. As we develop proposals for a long-term solution, the losses would be considered in analyzing the institutions needs.

MEHARRY MEDICAL COLLEGE

Question: I understand that the National Advisory Council on Health Professions Education has been investigating the financial situation at the Meharry Medical College. What has this fact-finding team learned?

Answer: The special Task Force on Meharry has established that (1) Meharry is a significant national resource for training disadvantaged minorities--43 percent of all black medical and dental graduates over the past 50 years are from Meharry; (2) Meharry is in extremely serious financial difficulty, and without substantial outside support will be forced to close; (3) the mission of Meharry is unique and the training opportunity for disadvantaged minorities which it provides would be lost if it is allowed to be closed; and (4) an infusion of funds alone will not solve the problems which face Meharry. Fiscal support must be accompanied by markedly strengthened management capability.

Question: How much support from HRA will be required by the School over the next several years?

Answer: The current debt of Meharry is approximately $11 million for loans, vendor payments, accrued expenses, and United States Letter of Credit. There is also a construction loan of approximately $30 million payable over the next 20-25 years. Several years of support are required in order for Meharry to achieve financial stability. With continued operating deficits, up to $10 million per year will be required over the next 6 years. The exact amount of this support will be dependent upon the success of management changes. However, it is important to note that there are other sources of possible support which must be investigated, such as the city of Nashville, and the state of Tennessee.

Question: Could you bring the Committee up to date also on the Tuskegee and Xavier Schools' needs for additional funds?

Answer: Based on submissions of these schools, management reviews, and a recent site visit by staff and consultants of the Bureau of Health Manpower, it was determined that current and projected deficits of these schools can be shown to result from fixed and needed expenditure commitments coupled with a lack of income producing capabilities. The deficits are definitely not attributable to mismanagement. The basis of support available to these schools is not sufficient to provide revenues to offset costs incurred in maintaining accreditation and providing special education to this unique student population.

In recent reports, Tuskegee provided a 5-year budget projection showing that the proportion of deficit spending over these years will increase significantly so that by the school year 1982-83, the School will have accrued a deficit of $7 million. Our analysis of the situation corresponds to this conclusion. Over the same period, Xavier University projects an accrued deficit of over $4 million. Again the trend is an ever increasing proportion of deficit spending with no reversal of this trend indicated in the 5-year projection. Based on our analysis, this expenditure would only be sufficient to maintain the school at the minimum level of acceptability for accreditation. I feel that much needed increases in key faculty salaries, the addition of needed support staff, the addition of facilities for a revenue producing laboratory, and a need to upgrade other parts of the educational system are needed to provide even an average educational environment. Such improvements would require at least an additional $1 million over this 5-year period, bringing the recommended funding over this period to $5 million.

My conclusion is that both of these schools cannot and do not predict financial stability and self-sufficiency at the end of the 5-year period presented. At best, by 1983 these schools should be able to show a steady decline in deficit spending leading to self-sufficiency by the late 1980s.

Question: Are these schools becoming dependent on Federal funding?

Answer: Of the three schools, only Meharry is already dependent on Federal funding for survival and long-term maintenance of their schools of medicine and dentistry. While there are no good predictors of eventual self-sufficiency on the part of these schools, a potential exists for employment of fiscal management and administrative policies that should lead to significant improvements over the next several years. Unfortunately, in order to assess the eventual abilities of the school to match revenues to expenditures after withdrawal of Federal support, it will first be necessary to bring the school out of the current stifling financial situation in which it is mired. A period of operation, after the removal of overwhelming debt and after the installation of new management personnel, policies, and procedures, will be required to determine whether the schools will be able to operate independently and not as fiscal wards of the Federal Government. At the University of

Tuskegee, School of Veterinary Medicine and at Xavier University, School of Pharmacy, the cause and effect relationships are much clearer. In the past several years these two schools have adopted and implemented management and fiscal policies and procedures which are exemplary. The emerging picture is now one of increasing needs for expenditures to meet obligations of accreditation and program expansions while the schools must draw upon traditionally poor revenue sources. Their fiscal problems are of a more serious nature and of a longer duration than most schools under financial distress and probably require a more targeted solution than the financial distress program provides. I anticipate, on the basis of the predictors evident at these schools that the situations can probably be turned around in the next 5 years. Support after this time should be of a diminishing nature and will eventually not be required. This is not to say, however, that funding to the extent needed by these specific schools will provide a total solution to a growing national problem. It is felt that if inflation continues, if Federal funds from other programs diminish, and if additional schools are started with insufficient funds to establish and maintain a sound program, there will be other small, private schools serving financially disadvantaged students and communities that will be unable to raise revenues to offset the growing costs associated with the operation of medical and other health professions schools.

Question: Are there any further developments concerning the financial plight of Tuskegee, Xavier and Meharry?

Answer: All three schools have reported an increase in deficit spending in 1980 over the previous year and the budget projection for a 5-year period shows a steadily increasing proportion of deficit spending. The Secretary in response to the requests of both the House and the Senate Committees on Appropriations, is currently gathering information to compile an indepth analysis of the situation of each of these schools and to prepare recommendations for a long-term program to alleviate the financial plight of these schools to insure they are provided every opportunity to become self-sufficient. In order to alleviate the present financial crisis of these schools to allow time to prepare recommendations for future actions, the award date for financial distress grants was moved forward to February 1, 1979. Each of the schools were awarded funds under this program.

Question: What have they done to improve their fiscal health.

Answer: A peer management review has either been undertaken or will be undertaken to identify the need for specific management improvement and fiscal control. There has been substantial increases in fund raising activities and goals have been set for producing revenue in this manner. The schools are acting to improve their fiscal management capabilities and to strengthen their staff in this area. The schools are investigating every potential source of income while attempting to maintain current tuition levels for the benefit of their students who are predominantly financially disadvantaged. The schools are relying very heavily on the possibility of special legislation for appropriations from the Congress in supporting the operations of schools with special purpose missions.

Question: Do you see the Federal government becoming more and more involved in health professions schools where a stable base of financial support is gradually eroding?

Answer: We project that if appropriations were significantly decreased in three major sources of funds, namely capitation, scholarship, and, the categorical, discretionary, and non-discretionary program support grants, some increase in financial distress applications would probably occur.

Question: As a matter of policy, do you believe the Federal Government should give funds to schools which have received assistance for more than two successive years?

Answer: The past history of the Financial Distress Program demonstrates the effectiveness of the program in alleviating short-term financial problems incurred by most schools which have applied for assistance. For 27 of these schools, the average funding period has been 2.46 years. At the same time, the program has had little success in resolving the financial difficulties of a certain class of schools which are defined as small, private schools serving a community with an inordinate low income populace. Four such schools have received financial distress grant awards each of the 8 years the program has been in existence.

We do not feel financial distress support should be restricted to a pre-determined period of funding. The uniqueness of each school's situation requires that determination be made on a case-by-case basis as dictated by the circumstances of each case.

STUDENT ASSISTANCE ELIMINATION

Question: Student assistance loans are proposed for termination in 1979. This would eliminate support for 8,300 students. What portion of these students are expected to turn to scholarship programs with a service requirement -- such as the NHSC Scholarship program?

Answer: Application to the National Health Service Corps Scholarship Program are purely on a voluntary basis of the applicant. The scholarships are not awarded based on financial need, consequently we do not know what portion of students who previously received loans will apply to this program. However, since 68% of students receiving loans are from families whose income is $12,000 or less it is assumed that some of these students will apply for highly competitive National Health Service Corps Scholarships.

Question: Are the balance of these students expected to obtain support from alternate sources or are some expected to terminate their medical educations?

Answer: These students will have the opportunity to apply for financial aid under programs administered by the Office of Education such as the Health Education Assistance Loan (HEAL) and the National Direct Student Loan Programs provided the schools participate in these programs. Programs of student support are also available through some state appropriations. In addition, loans will continue to be available from the repayment revolving funds previously established in the schools. We cannot determine at this time how many, if any, medical students would terminate their education.

COORDINATION OF NATIONAL HEALTH SERVICE CORPS PROGRAM

Question: Do any problems exist in the coordination of efforts between the National Health Service Corps (NHSC) and the Bureau of Health Manpower (BHM)? The NHSC is under the authority of the Health Services Administration while its scholarship program is administered by BHM under the Health Resources Administration.

Answer: The Bureau of Health Manpower has continuing and frequent liaison with the Bureau of Community Health Services (BCHS) in order to coordinate the two activities. Program-level staff conferences are conducted almost weekly and phone-contacts are on a daily basis. Increased use of speaker-phone meetings and word-processor telecommunications links are being planned to eliminate travel time and improve the flow of information between BHM and BCHS.

Question: Do any plans exist to transfer the responsibility for the Corps from the HSA to the HRA?

Answer: No plans have been made for such a transfer.

Question: What has been the impact of the NHSC? Cite statistics.

Answer: Information from the National Health Service Corps Program indicates that in 1978 there were a total of 1,289 assignees in the field. 694 of these assignees were physicians, 210 were dentists and 385 were other health professionals.

NATIONAL HEALTH SERVICE CORPS SCHOLARSHIPS

Question: Why originally were VOPP schools excluded from the NHSC Scholarship Program?

Answer: The statute authorizing the Scholarship Program specifically restricts the health-related disciplines participating in the Scholarship Program to medicine, osteopathy, dentistry, nursing, and other disciplines "needed by the National Health Service Corps." Although the Corps has identified its staffing needs over the years to the Bureau of Health Manpower (BHM) for inclusion in the Scholarship Program, the Corps has never indicated a need to secure veterinarians, optometrists, podiatrists, or pharmacists.

The Corps' manpower needs are determined by the requests for health professionals it receives from health manpower shortage areas throughout the country and the extent its resources can meet these requests. Accordingly, the Corps gives greatest priority to employing those disciplines which can best serve the health care needs of the greatest number of people: primary care physicians and general practice dentists. An increasingly large proportion of these Corps practitioners come from the National Health Service Corps Scholarship Program.

Question: How successful have the efforts been to make National Health Service Corps scholarships available to VOPP schools?

Answer: The Scholarship Program will have about 180 awards available for students of veterinary medicine, optometry, podiatry, and pharmacy for the 1979-80 school year. These awards will be distributed in proportion to the total number of practitioners of these disciplines needed in identified health manpower shortage areas. The Scholarship Program anticipates no difficulty in securing an adequate pool of Scholarship applicants from schools of the VOPP disciplines by the June 1 application deadline. It is notifying the schools during March of the awards available, contingent upon the publication in the Federal Register of the Surgeon General's announcement, now in preparation, of their participation this year. The large number of requests for applications from students of these disciplines received thus far is evidence of their high interest in this Program.

Question: In last year's report, the Committee directed that National Health Service Corps scholarships be awarded to students of veterinary, optometry, podiatry, and pharmacy schools. How many students of these disciplines are currently recipients of NHSC scholarships?

Answer: Awards of National Health Service Corps scholarships have not yet been made because funds appropriated for Fiscal Year 1979 will be obligated for the 1979-80 school year during the summer of 1979. The Scholarship program will have about 180 awards available for students of veterinary medicine, optometry, podiatry and pharmacy for the school year 1979/80.

NATIONAL HEALTH SERVICE CORPS SCHOLARSHIPS

Question: What has the Health Resources Administration done to see that National Health Service Corps scholarships do not go primarily to students attending private urban medical schools with high tuition who are unlikely to establish a permanent practice in underserved communities?

Answer: Special recruitment activities for the Scholarship Program are now being conducted jointly by Bureau of Health Manpower and National Health Service Corps staffs from both central office and all ten regional offices of the Department of Health, Education, and Welfare. These activities are attempting to increase the number of Scholarship applications received (a) from pre-medical students of undergraduate schools in the 15 States with the highest health manpower shortages, and (b) from students of medical schools which presently have less than 20 Scholarship participants.

Question: Has any action been taken to increase the number of scholarships to be awarded to students enrolled in these specialties?

Answer: By statute, up to 10 percent of the funds appropriated to National Health Service Corps (NHSC) Scholarship awards may be used for disciplines other than medicine, osteopathy, and dentistry. The NHSC had already indicated an identified staffing need for 290 baccalaureate nurses, master's level nurse-midwives, community health nurses, nurse practitioners, and public health nutritionists. The funds remaining will cover about 180 awards for distribution to students of the veterinary, optometry, podiatry, and pharmacy (VOPP) disciplines for the 1979-80 school year.

EXCEPTIONAL FINANCIAL NEED SCHOLARSHIPS

Question: Why has your agency eliminated "Exceptional Need Scholarships" in 1980, generally used to help black and minority students attending medical school?

Answer: In 1980, priority is given to programs, namely; the National Health Service Corps Scholarship, Primary Care Residency Training and Family Medicine, which can more effectively address the problem of maldistribution. Minority students are eligible to receive National Health Service Corps scholarships.

Question: What is the effect of this action?

Answer: Students who had previously received first-year scholarship support under the Exceptional Financial Need program will be eligible for priority consideration under the National Health Service Corps Scholarships in seeking scholarship aid for their 2nd year and beyond. In addition, the provisions of the law will require that, in Fiscal Year 1980, individuals entering their first year of study receive priority for Corps scholarships. Students will also be eligible to apply for Health Educational Assistance Loans in the Office of Education.

DENTAL AUXILIARIES

Question: To what extent are Expanded Function Dental Auxiliaries (EFDAs) used to complete restorations in Federally operated dental care delivery programs administered by the various Public Health Service component organizations?

Answer: At the present time at the Coast Guard Recruit Training Centers at Cape May, New Jersey and Alameda, California and at over thirty Indian Health Service Clinics, Expanded Function Dental Auxiliaries (EFDA) are utilized to place, carve, and finish dental restorations. Each of the other Public Health Service dental care programs is actively considering the use of such auxiliaries where the work load and resources make such activities practical. The Indian Health Service conducts a training program for EFDA and the Director of Hospitals is in the process of establishing a training activity at its New York City Out-patient clinic in other advanced functions.

Grantees in the Neighborhood Health Centers, Migrant Health Centers and other direct care grant-funded activities are governed by applicable State Dental Practice Acts. In these States, the decision to use EFDAs is the responsibility of the dental provider and the sponsoring agency.

Dentists assigned to dental manpower shortage areas by the National Health Service Corps are encouraged to use EFDAs where appropriate.

Question: What are the barriers prohibiting dentists in the private sector from employing and using EFDAs to complete restorations and what is the Health Resources Administration doing to deal with such barriers?

Answer: The following are barriers inhibiting practicing dentists in the use of Expanded Function Dental Auxiliaries (EFDAs) to complete restorations, and actions being taken by the Health Resources Administration (HRA) to deal with the barriers:

The most significant barrier to use of EFDAs is the decrease in demand for dental care which has resulted from the present economic situation. Dentistry more than other health services is sensitive to economic pressures. Until there is an infusion of money into the dental market or a system to aid the public to meet their dental needs, thereby stimulating demand, dentists will not readily expand their practices or delegate additional duties to auxiliaries. Though HRA assesses the factors related to health care supply and demand, it is for the purpose of determining health manpower requirements and projections. It has not been within HRA's functions to initiate means to stimulate, regulate or redirect market demands or monies.

Many practicing dentists are unprepared to use Expanded Function Dental Auxiliaries (EFDAs). HRA is funding 24 dental schools through

grants, to train students in the skills necessary to effectively use EFDAs. In addition, HRA continues to disseminate materials designed to aid practicing dentists in the use of EFDAs.

There is a limited supply of auxiliaries trained in expanded functions. Through grants, at present HRA is funding 21 dental auxiliary programs to train 850 students in expanded functions. Over 50 dental auxiliary faculty are being prepared to provide training in expanded functions, and high quality educational materials are being disseminated through outside agencies.

Many State dental practice acts do not permit auxiliaries to complete restorations. HRA regulations/guidelines for grant programs give special consideration to applications proposing the broadest delegation of intra oral functions to auxiliaries. Also through the training programs described above, personnel are being produced who are likely to press for appropriate changes in dental practice acts when warranted by an increase in demand for dental care.

Some changes in dental practice characteristics are necessary to effectively use EFDAs. HRA is conducting studies concerning the economic impacts of the use of auxiliary personnel in dental practice. Practice characteristics beyond that of economic impacts remain yet to be clarified.

Question: What impact would full employment of EFDAs in the private sector to complete restorations have on the amount and type of future Federal financial support for dental manpower training?

Answer: Full employment in the private sector of Expanded Function Dental Auxiliaries (EFDAs) to complete dental restorations could increase the output of restorative dentistry by 80%-130%, based on research findings. Employment of EFDA's also has the potential for containing costs of dental care, and improving the scope and mix of primary care services provided by the dentist.

The type of future Federal financial support for dental manpower training should be directed toward preparing dentists to utilize auxiliaries and provide a broader range of skills that would improve the continuity of preventive and primary care services, and toward research and development projects related to potential auxiliary roles in other critical areas of dental need, such as denture care services, prevention and periodontal maintenance, and care for the elderly.

DENTAL ACTIVITIES

Question: What was the reorganization of HRA's Division of Dentistry intended to accomplish?

Answer: The Division of Dentistry was reorganized as a part of a larger reorganization of Health Resources Administration which was intended to better align available resources within Agency functions. Specific to the Division of Dentistry, the reorganization was intended to (1) Consolidate all health manpower analysis activities within the Bureau of Health Manpower from the categorical Divisions (including Dentistry) into a Division of Manpower Analysis at the Bureau level and (2) redireet delivery systems research activities within the Division of Dentistry to higher priority program areas within Health Resources Administration.

Question: It appears that you have consolidated some activities. Is any reduction in resources associated with this consolidation (dollars and positions)?

Answer: There has been a reallocation of resources associated with the consolidation of activities. However, there will be more efficient and effective use of limited resources because of the consolidation of activities and additional benefits will be gained by redirecting scarce resources.

REGIONAL DENTAL EDUCATION

Question: What steps have been taken to establish a Regional Dental Education Program in the Pacific Northwest as recommended by the Committee in last year's report?

Answer: A competitive contract has been prepared and is expected to be awarded late in the third quarter of this fiscal year. The contract is intended to fully carry out the Committee's recommendation.

PHYSICIAN EXTENDERS

Question: What are some of the obstacles to the increased use of physician assistants and nurse practitioners?

Answer: Significant issues affecting physician assistant and nurse practitioner utilization emanate from legislation governing these practitioners. These issues are: legal recognition; method of state regulation; use of national standards for regulation; identification of specifically prohibited or permitted procedures; requirements for physician supervision; and authority to prescribe or dispense drugs. Reimbursement of nurse practitioner and physician assistant services by third-party payment programs, government or private, is a major barrier to the full utilization of the services of these individuals. One law has been passed which may be helpful. Public Law 96-210, Rural Health Clinic Services Act, signed by the President on December 13, 1977, authorizes reimbursement under Medicare (Part B) and Medicaid for services provided by nurse practitioners and physician assistants in certain rural health clinics.

Question: What has been the effect of legislation which provided Medicare and Medicaid reimbursement for physician extenders in rural health clinics?

Answer: It is somewhat premature to try to measure the effect of the Rural Health Clinic Services Act at this time. Initially, however, it appears that forty-two states would be affected by the Medicare section of this act because they do permit nurse practitioner and/or physician assistant practice through additional acts, amendments, and/or physician assistant regulatory statutes. In addition, five states with general delegatory amendments could be affected depending on the interpretation of those amendments.

The Medicaid amendments would have a slightly different impact because fourteen states already reimburse for nurse practitioner/physician assistant services in rural health clinics. On the other hand, eighteen states would be affected because they do not reimburse for either nurse practitioner or physician assistant services. Nine other states might be affected because their current policies are not explicit even though payment is made. Six other states who do pay for nurse practitioner and/or physician assistant services would be affected because they do not reimburse clinics directly.

The major impetus for amending Medicare and Medicaid legislation came from rural health clinics which employ physician assistants or nurse practitioners who practice under protocol rather than on-site supervision. The Rural Health Clinic Services Bill was clearly designed to reimburse those clinics. Even among those states which have physician assistant and/or nurse practitioner legislation, the legal status of these clinics is unclear because requirements for supervision are so poorly defined in state law.

PHYSICIAN EXTENDERS

Question: How many physician extenders exist in this country today?

Answer: There are currently 15,633 physician extenders; 8,000 nurse practitioners and 7,633 physician assistants.

Question: How many have been placed in Health Manpower Shortage Areas by the NHSC?

Answer: A total of 311 physician extenders have been placed in Health Manpower Shortage Areas by the National Health Service Corps; 205 nurse practitioners and 106 physician assistants.

Question: What efforts are being made to strengthen training programs for physician extenders?

Answer: The Division of Medicine is utilizing a multifaceted approach to strengthen training programs for physician extenders. The Area Health Education Centers, funded under section 781 of the Public Health Service Act, requires that each medical or osteopathic school participating in an area health education center program shall be responsible for, or conduct, a program for the training of physician assistants or nurse practitioners.

The Grants for Physician Assistant Training Programs, under section 783 of the Act, provides funding preference to programs which are conducted in conjunction with other programs training primary care physicians in a manner which shares educational resources and encourages the utilization of physician assistants by physicians. Some 45 grants totalling $8.7 million were awarded to support the training of assistants to the primary care physician. Approximately 2,330 trainees were enrolled in the programs in 25 States and the District of Columbia during the 1978-1979 school year. The training of 71 faculty members was also supported. Since this program began in fiscal 1972, the Bureau of Health Manpower has supported the training of approximately 6,000 physician assistants.

Almost $13 million was awarded in fiscal 1978 to encourage institutions to train nurse practitioners and to assist nurse practitioner trainees. Eighty nurse practitioner training programs received a total of $11.6 million in grants. About 1,245 students including 513 who graduated during the year were enrolled in the funded programs. Nurse practitioner traineeships totaling $1.2 million assisted 238 students including some enrolled in Federally supported programs.

The Family Medicine Residency Program, under section 786 of the Act, encourages training with various types of health personnel, including physician assistants and nurse practitioners. All training programs within the Primary Care Education Branch encourage training and deployment in urban and rural health manpower shortage areas.

STUDY ON PHYSICIAN EXTENDER REIMBURSEMENT

Question: Recently, the GAO suggested that the Congress should reconsider the necessity for HEW to complete its study on physician extender reimbursement as required by the Social Security Act Amendments of 1972. What is presently the status of this report and what is your opinion of the GAO's recommendation?

Answer: The Study on Physician Extender Reimbursement was a three phased approach. The experimental design encompassed the development of: a baseline data set of primary practices (collected by the University of Southern California), both with and without physician extenders, to compare practice characteristics in terms of patients, services provided, charges for services--all prior to experimental reimbursement for physician extender services; a set of reimbursement formulae with sufficient range of reasonable rates to determine whether the reimbursement formula affects the use of the physician extender as a primary provider; and reiterative readings, through total practice counts and log-diaries, of the changes in physician/physician extender practices and procedures which may be attributable to physician extender Medicare reimbursement.

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The first phase of the project was implemented through a contract to the University of Southern California to collect baseline data. Phase 2 consisted of an evaluation contract to Systems Sciences, Inc., to develop a three-pronged approach to assessing quality of the care provided in participating practices, i.e., by interview, observation, and records review; a set of data on practice costs, particularly those attributable to the physician extender in the practice; on-site validation of the self-reported practice characteristics and procedures reported in the University of Southern California log-diaries; and assessment of the legality of physician extender activities.

The final phase of the project consists of in-house work to put all data collected on tape and into a computerized system. Phases one and two have been completed and part of the work in Phase three is completed.

Inasmuch as the bulk of the work has been completed, it is our expressed opinion that the study should be completed and not terminated at this point.

Question: How much money has this study cost so far and what will be the total cost of the study on its completion?

Answer: At the end of the study period, it is expected that the total cost of the study would be $1,337,000. Phase one was completed at a cost of $750,000; Phase two at a cost of $557,000 (which included a small add-on contract to manipulate the University of Southern California data); and Phase three cost is projected at $30,000.

Question: When is the study expected to be completed?

Answer: The study should be completed during the late summer of 1979.

CURRICULUM DEVELOPMENT IN INTERDISCIPLINARY TRAINING

Question: Are efforts being made to facilitate better training for health professionals in the areas of preventive medicine, geriatric medicine, and environmental and occupational health? Explain.

Answer: Efforts are underway to improve the training of health professionals in each of these areas. A brief summary of activities in each area follows:

Geriatric Medicine - A Curriculum Development Grant program has been initiated in fiscal year 1979 under the authority of Interdisciplinary Training program, Section 788(d) of the Public Health Service (PHS) Act. In response to Congressional intent the Bureau of Health Manpower has allocated two million dollars for geriatrics projects to be supported under this grant program. The purpose of the program is to facilitate efforts in grantee institutions to develop and implement new courses or segments of courses and training experiences devoted to the unique health care needs of the elderly especially emphasizing primary care. Awards to 25-35 applicants are expected in September.

In a more general sense, the Family Medicine (Section 786 of the PHS Act), General Internal Medicine and General Pediatrics (Section 784) and the Area Health Education Centers (Section 781) programs provide funding which will have a positive impact on the delivery of health care to the elderly by addressing the problems of geographic and specialty maldistribution as recommended curricular components. In addition, some participants in these programs have started programs targeted to the specific needs of the elderly. A total of $76,000,000 was appropriated for these programs in FY 1979.

In addition, the Bureau of Health Manpower has used the contract mechanism to support initiatives in the following areas; training of geriatric nurse practitioners and geriatric nurses, continuing education for nursing home nurses, study to determine the effect of fluoridation on the demand for dental health care among the elderly, preparation of long-term care administrators, study of alternative methods of increasing the geriatric aspects of the pharmacy curriculum, development of an educational program in rehabilitative optometry, and humanistic medicine. Additional contracts in the area of geriatrics curriculum are being developed for award in FY 1979.

Environmental and Occupational Health - The Curriculum Development Grant program discussed above will also support projects to facilitate the incorporation of environmental and occupational health concepts into the curricula of medical and osteopathic schools. A total of one million dollars is allocated for this purpose in FY 1979.

Under Allied Health Project program, Section 796 of the PHS Act, project grants and contracts are authorized for allied health personnel including environmental health personnel including environmental health at the associate and baccalaureate levels. Public Health Traineeship program, Section 748 as amended, permits the Secretary to make traineeship (student assistance) grants to accredited schools of public health and other public or nonprofit institutions which provide graduate or specialized training in public health, including environmental health. In 1978, $6,473,759 was awarded through formula grants to schools of public health for student assistance. It is estimated that approximately 1.5 million dollars was awarded for support of environmental health trainees. Special Projects for Public Health and Graduate program in Health Administration, Section 792 of the PHS Act, provides for the award of projects grants to enrich a broad range of public health curriculums (e.g., epidemiology, biostatistics, health administration) including environmental health in any public or nonprofit educational entity offering graduate level degrees. In 1978 twenty-two grants at a level of $1,125,000 were awarded under Section 792 to programs in environmental health located in schools of public health.

The Health Training Improvement Act of 1970 (P.L. 91-519), reenforced by the Health Professions Educational Assistance Act of 1976 (P.L. 94-484), provides a base for efforts directed toward assuring the competencies of allied health practitioners, including environmental health practitioners. Its focus is the development of credentialing mechanisms, and its emphasis is on the performance requirements essential for competent practice.

The Bureau funded an investigation of the roles and functions of environmental health personnel which delineated the major and specific responsibilities of the field including the functions for each of three entry levels (technicians, technologists, administrators) in environmental health. Subsequent projects are designed to specify competencies necessary to execute the functions, develop a relevant curriculum guide, develop and test self-assessment instruments for environmental health practitioners, and test a criterion-referenced proficiency examination for environmental health personnel. The overall impact of these efforts, in addition to assuring individual practitioner competency in this arena, are intended to strengthen both initial and continuing education for the field in terms of relevance to the actual functions performed.

A contract was awarded to the University of Arizona in 1978 to identify the primary care elements in the practice of occupational, industrial, environmental and preventive medicine and to develop a model for integrating these elements in the training programs of primary care physicians.

Preventive Medicine - Support of project grants, to strengthen and expand the curriculum of medical and dental students in preventive medicine and community health, was enacted in 1960 under authority of the Project Grants for Public Health Training (Section 313 of the PHS Act as amended) and continued through 1977. Support of such grants were not continued under the Public Health Project Grant authorities (Section 792) of P.L. 94-484. Support provided under Section 313(a) authorities between 1970 and 1977 were as follows:

	Number of Medical Schools	Support for Preventive Medicine	Dental Schools	Support for Preventive Dentistry
1970	33	$1,257,248	16	$740,902
1971	23	1,063,391	15	750,687
1972	23	1,169,378	13	690,683
1973	14	709,401	13	584,314
1974 1/	13	1,598,677	8	873,423
1975	14	1,230,736	2	198,636
1976	13	1,129,481	2	196,584
1977	13	1,127,969	2	195,504

1/ Grants awarded in FY 1974 were funded for up to 3 years from 1974 appropriation and 1973 released funds.

Preventive medicine and dentistry residency training grants were authorized in 1957 under Section 312 of the PHS act and continued under Section 748 by P.L. 94-484. Preventive medicine and dentistry residency traineeships are designed to increase and improve the opportunity for physicians and dentists who have completed their basic professional training to prepare themselves for positions of leadership in this specialty area. In the period from 1970 through 1978 a total of approximately 230 residents in medicine and 90 in dentistry were supported by these traineeships.

The Bureau of Health Manpower is currently attempting to identify primary care elements in the practice of preventive medicine and to develop a model for integrating these elements in the training program of primary care physicians. Another contract has been awarded to identify and evaluate a program to educate primary care providers in patient education skills.

GOVERNMENT ACCOUNTING OFFICE REPORT - PHYSICIAN TRAINING

Question: Has the Department taken any action in response to last year's GAO report on the problems of training enough physicians of the right types in the United States?

Answer: To address the long range problems of physician supply and come up with long range solutions to the problems of specialty distribution, the Department established the Graduate Medical Education National Advisory Committee (GMENAC) in April 1976. The Committee charter was renewed until April 1980 by the Secretary

The Committee is developing specific strategies to address the problems of distribution of physicians by specialty and geography and is looking at several areas including: the financing of medical education; the educational process itself; and long range and continuing manpower planning.

Estimates of gross requirements of 15 specialty groupings are scheduled for completion October 1979. This will develop a set of personnel requirements for each of the specialty groupings based on the assumptions of providing full services to the U.S. population. By 1980 the Committee hopes to determine the future requirements in each of these specialties and come up with recommendations for bringing the distribution of graduate medical education training positions into line with the Nation's requirements.

The Committee is also examining those issues which affect all medical specialties through the use of technical panels on: financing medical education and the delivery of services; examining the role of non-physician providers of service; overseeing the development of the manpower models; geographic distribution; and the effects of educational environment on the choice of specialty.

Question: Has the Secretary of HEW discussed with the Coordinating Council on Medical Education the possibility of national studies on physician supply and requirements?

Answer: The Department has solicited viewpoints of the CCME as well as other interested bodies and is utilizing their opinions and recommendations to formulate a reasonable assessment of current and projected needs and develop effective goals. Included in the membership of GMENAC are members who are active participants in the parent organization of the CCME.

Question: Do you agree with the conclusions and recommendations of GAO?

Answer: Both the draft and final reports reflect the diversity of viewpoints concerning the adequacy of the present and future supply of physician specialists and how specialty maldistribution might be corrected. The final report also underscores the general agreement on the need for additional primary care physicians. Also, the final report appropriately emphasizes the research efforts, which must be undertaken to define and achieve a rational distribution of physician specialists.

The Department's comments on the draft report contained in the final report is basically the same. We concur in the need to work with the CCME but we believe that the CCME is not, as the GAO recommendations implies, the only appropriate source for conducting the studies and analyses needed. We will continue to solicit viewpoints of CCME and widely circulate reports, analyses, and studies in support of GMENAC.

EMERGENCY MEDICAL TRAINING

Question: You also propose to eliminate funding for emergency medical training. Why do you think the states should or would assume funding of these projects?

Answer: Emergency Medical Training, Section 789 of PHS Act, authorizes support primarily for training in four general types of emergency medicine professionals and each type has a somewhat different prospect for future funding. Each type is discussed below:

Emergency Physicians - A substantial amount of the training of emergency physicians is centered in clinical experiences in emergency rooms. Many of the educational experiences of residents in emergency rooms are service reimbursable (either third party carrier or direct patient reimbursement). It is anticipated that this service/training reimbursement environment will provide some funds for the educational expenses relating to the training of emergency medicine residents.

Emergency Nursing Personnel - The training of emergency nursing personnel was addressed under Section 789 through grant and contract support. The training experiences under this support were directed mainly toward continuing education. It has been the Department's and Agency's thesis for several years that continuing education for paid health manpower professionals is the responsibility of the professionals themselves.

Emergency Medical Technicians-Paramedic - In a significant number of Paramedic training programs, tuition and fees are currently being charged to the paramedics themselves. It is anticipated that the paramedic training program can continue to be a viable training program under a tuition and fee arrangement between the potential paramedic and the university/college.

Emergency Medical Technicians-Ambulance - It has been the experience under the administration of Section 789 that many of the EMT ambulance training programs are voluntary and viewed to a large degree as a community service. It is anticipated that there is a minimal need at this point in time to continue the EMT Ambulance Training Program and that those needs can be addressed by volunteerism and community support. In addition, States that place a high priority on EMT ambulance training may choose to allocate additional National Highway Traffic Safety Administration funds or State funds to support these training programs.

AREA HEALTH EDUCATION CENTERS (AHEC's)

Question: Your agency's Area Health Education Centers (AHEC's) are intended to address the major problems of geographic maldistribution and overspecialization of health professionals by fostering changes in the pattern of education. Considering that there are 18 previously-funded AHEC's and 3 new starts planned in 1979, how do you intend to continue all these projects in 1980 with the $5.8 million included in your budget request -- especially since you mention that you are planning 2 additional new starts in 1980?

Answer: At present there are 18 previously-funded Area Health Education Centers and 6 new starts planned in 1979. However, the Department does not intend to fund all AHEC programs in 1980 with the $5.8 million in our budget request.

Of the ongoing AHEC projects in FY 1980, we will utilize the following criteria to determine high priority projects for continuation:

1. Whether the project meets or will meet criteria as required by statute and program regulations.

2. The project's success in meeting the current performance requirements. This criteria will be used as an indication of readiness to proceed and potential for successful performance in subsequent years.

3. The extent or severity of the need for health manpower resources in the area or for the populations to be served. Health manpower shortage or medically underserved area designations will be used as the primary indicators of need.

4. The extent to which non-Federal funding has been available (in excess of the minimum 25% match required).

Using these criteria, the Department anticipates that approximately 10 of 24 AHECs could be continued. Therefore, no new starts would be initiated in 1980.

Question: How much money was included for 1980 in your original spending plan for the AHEC program?

Answer: In the original AHEC spending plan, the 1980 amount was $19,000,000. Included in this amount was support for the 11 original AHEC's and support for 11 additional AHEC's whose funding would have started in 1977 or thereafter. Finally, support would have been provided for two new AHEC's in 1980 under this original plan.

Question: Why are you planning new starts when you are not able to support existing projects with the resources requested?

Answer: The 1979 appropriation for the Area Health Education Center program earmarked funds for new AHEC starts in 1979. In planning these new starts, the Department feels it is carrying out the explicit intentions of Congress.

SPECIALTY MALDISTRIBUTION

Question: Has the proportion of the physicians in the primary care fields increased significantly in the past few years?

Answer: The total number of primary care physicians has increased from 110,071 in 1963 to 135,881 in 1976. Data concerning primary care physicians as of 1978 are in the process of being compiled.

The Bureau of Health Manpower training support is assisting in increasing the number of practicing primary care physicians. For example, of the current estimated 6,238 family practice residents in training, 4,114 or 66% is estimated to be enrolled in programs supported by the Bureau. Through the Bureau, Grants for Residency Training in General Internal Medicine and General Pediatrics, 900 primary care residency positions are currently being assisted. The total impact of these programs is either under evaluation or planned for evaluation.

Question: What has the Health Resources Administration done to stimulate interest in this field among medical students today?

Answer: During fiscal year's 1972-77, Health Professions Special Projects under, Section 772 of the Public Health Service Act supported training in primary care including clerkships and preceptorship programs

Under Primary Care program, Section 784, grant funds are provided to support the creation of new residency positions and/or facilitate the conversion of traditional programs to those which emphasize the provision of longitudinal, preventive, and comprehensive care.

Under Family Medicine program, Section 786 of the Act, grant support is intended to promote the graduate education of physicians who are trained for and will enter the practice of family medicine. Three grant programs are ongoing under this authority: Grants for Residency Training in Family Medicine, Grants for Predoctoral Training in Family Medicine and Grants for Faculty Development in Family Medicine. These grants require programs to emphasize the provisions of longitudinal, preventive and comprehensive care to families.

Primary Care and Family Medicine training programs provide stipends to residents participating in the grant programs. Additionally, both programs encourage utilization of sites in Health Manpower Shortage Areas. It is anticipated that these programs will have a considerable impact on the training of primary care physicians over the next few years.

Question: Could you please supply specific numbers pertaining to increases in internal medicine and pediatric residencies and their impact on the total number of general/family practitioners currently in the United States?

Answer: During fiscal year 1977, the Bureau of Health Manpower assisted programs providing 742 residency positions in primary care medical specialties of general internal medicine and general pediatrics. This number increased to 900 in fiscal year 1978.

Out most recent data (1976) on practicing internists and pediatricians show the following change: in 1963, there were 30,434 internists and 12,762 pediatricians and figures as of 1976 indicate that there are 57,911 internists and 22,491 pediatricians.

PODIATRIC MEDICINE

Question: In a special report to the Congress on the status of the nation's health professions personnel (August 1978), the Department of Health, Education, and Welfare projects that by 1990 the numerical supply of most health professionals will reasonably equal their demand. This is true, according to the departmental report, except for doctors of podiatric medicine, who will continue to be in short supply in 1990. Furthermore, the report states that the geographic maldistribution of podiatrists, which is the most uneven of all the professions, shows few signs of improvement during the next decade. Given these admissions, the Committee is interested in knowing the Department's present and long range plans in countering these adverse trends in podiatric medicine.

Answer: The Health Resources Administration is presently in the process of developing a Health Manpower strategy for meeting the needs of the nation in the 1980's. The needs within podiatric medicine are included in the strategy being debated and developed within the Department.

NUTRITION EDUCATION

Question: What portion of the 1979 amount appropriated for interdisciplinary training has been allocated to the development of education programs in human nutrition?

Answer: Of the $7.1 million appropriated for Section 788(c) and 788(d), $1.5 million has been allocated for educational programs in human nutrition in FY 79.

Question: Has a competitive grant program been developed to provide support to those institutions willing to initiate or expand their nutrition programs?

Answer: A competitive grant program has been initiated to support nutrition education in the health professions. The Bureau has distributed approximately 2,000 grant applications under the Curriculum Development Grant Program. A significant portion of those have been requested specifically for nutrition education. Awards will be made in September 1979.

Question: Please summarize for us the conclusions of the Report which we requested on the development of nutrition courses for health professionals.

Answer: Senate Report 95-1119 required the Secretary to report the progress of developing nutrition courses for health professionals at the time of next year's hearings. A report has been submitted to the Appropriations Committee. In summary, that report describes the current status of nutrition education in the health professions schools and the lack of physicians who provide a role model of sound nutritional care practice. It also describes the Department's efforts in the area of nutrition education for health professionals including the grant program mentioned previously, the health professions special project grants to develop required or elective nutrition courses in allopathic and osteopathic schools of medicine, the Bureau's contract to evaluate nutrition curricula in nine medical schools, the development of an annotated bibliography on nutrition education in the U.S. medical schools, the contract with Ohio State to develop 15 self study packages in nutrition for family practice residents, the inclusion of nutrition modules in the family practice residency grants, the training of dietitians and nutritionists under the allied health and public health provisions of the health manpower authorities, the continuing education programs in nutrition supported by the Maternal and Child Health Program, and a Food and Drug Administration contract with the University of North Carolina to develop self instructional packages in nutrition for several disciplines in the health field.

CONCENTRATING RESOURCES IN PRIMARY CARE

Question: Dr. Foley, the subcommittee received a copy of a letter addressed to you from Dr. Rodowskas, the Executive Director of the American Association of Colleges of Pharmacy. He believes that the Administration is moving in the wrong direction by concentrating resources to support primary care physicians. Dr. Rodowskas is a proponent of expanded roles for pharmacy and other health professions which he claims would improve patient access and contain costs. Has your agency rejected this approach, and if so, why?

Answer: We certainly support the concept of expanding the role of health professionals in the delivery of services. Teaching the clinical pharmacist role has been encouraged as well as being required under the capitation grant program. This has included: an inpatient and outpatient clerkship experience in a hospital, extended care facility, or other clinical setting--instruction with physicians and other health professions--training in the counseling of patients with the regard to the appropriate use of and reactions to drugs and--training in drug information retrieval and analysis in the context of actual problems.

These areas do represent expanded roles for pharmacists and certainly do require increased patient contact.

Question: Has HRA considered promoting the health delivery system consisting of a team of health professionals?

Answer: The Bureau of Health Manpower in the Health Resources Administration has supported two contracts and sixteen grants since fiscal year 1973 to develop and promote interdisciplinary team training for primary care. Seven projects were funded for this purpose in fiscal year 1978.

The Health Resources Administration position is that with the increasing complexity and rapid growth of knowledge and technology in the health care system, the need for interdisciplinary team training will increase. It is a reasonable way of teaching health professionals to work effectively together to eliminate professional overlaps and help contain health care costs through greater efficiency.

NURSING RESEARCH

Question: How many nurse researchers are on National Institutes of Health review committees?

Answer: There are at least four nurse researchers on the National Institutes of Health committees.

Question: The Nursing Research Grants Program does not contribute to the proliferation of health professionals and supports worthwhile research projects throughout the country. Why has this assistance-- Research Grants Program been proposed for rescission in 1979 and elimination in 1980?

Answer: The proposal for the rescission of assistance for the Research Grants Program in 1979 and its elimination in 1980 is requested because a higher priority is assigned to programs of specialty and geographic maldistribution of health professionals. In addition, much of this type of research can be funded by the National Center for Health Services Research.

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Question: Will the amounts requested for 1979 and 1980 provide funding for all continuations?

Answer: The rescission request, if approved, will mean that 22 ongoing non-competing continuation grants for a total of $3,301,000 will not receive support in fiscal 1979. The elimination of funding in 1980 for research grants will mean that seven ongoing, non-competing continuation grants for a total of $803,000 will not receive support.

Question: Doesn't it seem a bit foolish to delete the very small nursing research program that can directly lead to improvements in care?

Answer: Because of limited funds available, some choices had to be made and we believe that a higher priority should be assigned to specialty and geographic maldistribution of health professions.

Question: What funding is required to fund all non-competing nursing research projects in fiscal 1979?

Answer: The funding required to support the 32 non-competing continuations for nursing research projects in fiscal 1979 is $4,400,000.

Question: How about the funding of current fellowships and institutional awards for research training?

Answer: The funding required to support the 91 non-competing continuation nursing fellowships and the three institutional awards in fiscal 1979 is almost $1,000,000.

ANNUAL FEDERAL EXPENDITURE ON NURSING RESEARCH

Question: How much does it spend on nursing research and other research specific to the actual delivery of nursing care?

Answer: The amount appropriated by Congress for nursing research grants administered by the Division of Nursing was $5,000,000 in fiscal 1978. There is also research in other agencies that pertain to nursing, but we do not have an estimate for that amount. This research is part of other kinds of effort and does not only pertain to the delivery of nursing care.

ANNUAL FEDERAL EXPENDITURE ON NURSING CARE

Question: How much money does the Federal Government spend on nursing care annually?

Answer: Based on the number of actual nurses involved in nursing care and the number of nursing aides and practical nurses, the estimate of annual expenditures is $7 billion.

REGULATIONS TO IMPLEMENT NURSE TRAINING ACT OF 1975

Question: I understand that HEW finally published regulations to implement the Nurse Training Act of 1975. But these regulations became effective only five days before the law expired. What possible explanation can you offer for this delay?

Answer: The Administration requested input into the regulatory process from the profession and from the public and the significant differences between the interests expressed by both the profession and the public on the one hand, and the priorities of the administration on the other, resulted in unpredictable delay.

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ADVANCED NURSE TRAINING

Question: Nursing Department budgets are often in the multi-million dollar category. How many nurse administrators have preparation at the graduate level?

Answer: Of the nurse administrators, about 9600 or 20% of the total number are prepared at the graduate level.

Question: Isn't it reasonable to expect that cost savings of real significance could come from better preparation of those nursing directors?

Answer: It is reasonable to believe that individuals educated to do a job are able to do it better than those who are not so prepared. We have no firm figures to indicate that there is a cost savings with proper education, but we do expect that there is some economic benefit and there is data which clearly indicates that the quality of patient care is increased in settings which have qualified nursing administrators.

NURSE TRAINEESHIPS

Question: Since few nurses make more than $15,000 - $16,000 a year and tuition for graduate school can run as high as $5,000 - $7,000, don't you think traineeships are still needed?

Answer: Certainly some form of support for some students may be needed. For those who do we will direct them toward the National Health Service Corps Scholarship program or student assistance programs administered by the Office of Education.

Question: In the student aid area, particularly, I notice that the President has proposed very major cutbacks in loans, scholarships and traineeships. How can you reconcile this with his promise of November 11, 1978, that no one would be hurt this year as a result of the Nurse Training Act veto as there is the continuing resolution?

Answer: Funding for Nursing programs is provided under the Continuing Resolution but since the demands for the limited resources available are so great, the President has decided to reallocate his resources and to provide additional funds to address the shortage area problem. Student assistance funds have not been entirely eliminated since an amount of $13,500,000 is provided for student loans. In addition, the Nurse Practitioner program, which was not rescinded, provides traineeship support. Also, student loan funds are available at Nursing schools from their loan revolving funds which totaled $9,500,000 in 1979. The enactment of the Middle Income Student Assistance Act also provides nursing students an available source of funds from the Office of Education.

MINORITY ENROLLMENT

Question: In the FY 1979 hearings, it was stated that HEW was going to try and stimulate first-year enrollment of minorities in health profession training by encouraging an expansion of the size of the applicant pool. Has the HEW gone ahead with this policy?

Answer: The Health Resources Administration (HRA) currently administers two programs specifically designed to enhance health career opportunities for the disadvantaged: (1) Disadvantaged Assistance (Sections 787 and 798 of the Public Health Service Act); and (2) Educational Opportunities for Nursing Students from Disadvantaged Backgrounds (Section 820 (a) (3) of the Public Health Service Act). In addition, HRA administers two complementary programs; student loans and exceptional need scholarships for first-year students. Efforts are also made, within the framework of the legislation, to address the needs of the disadvantaged throughout all the Agency's programs.

The Disadvantaged Assistance and Nursing programs, the primary beneficiaries of which are minorities, have established recruitment, preliminary education, facilitating entry, and retention as their priorities. Forty-three percent of all exceptional need scholarships for first-year students were awarded to minorities for the 1978-79 school year. Grants and contracts have been awarded to minority and non-minority undergraduate and graduate schools to expand recruitment efforts including the development of media and printed materials designed specifically for minorities, women, and rural youth.

The Department has implemented special Hispanic and Indian initiatives and HRA is in the process of developing a comprehensive and innovative access to health careers and services strategy which focuses on the needs of the disadvantaged and underserved.

Question: Has the expansion of the applicant pool meant a drop in applicant's quality?

Answer: It is too early to tell if our current efforts have significantly increased the applicant pool. With respect to the quality of the new applicants, we do not have any data. Historical evidence, however, leads us to believe that there will not be a drop in their quality. The retention rate of minority medical students has been improving over the years and is only slightly below that for white students. Medical College Admission Test and Dental Admission Test scores have also improved.

Question: If it has, have there been any problems with the effect of the Bakke decision?

Answer: As previously indicated, it is too early to tell if our current efforts have significantly increased the minority applicant pool, nor do we have any data on the quality of new minority applicants. In general, we do not know the effects of the Bakke decision. Although many individuals have expressed their concerns, we do not have any hard data to substantiate them. We have not noticed any decline in the total number of grant applications submitted by educational or other institutions which are designed to increase the number of minorities in the health professions.

DISADVANTAGED AND MINORITY STUDENTS

Question: How have the BHM efforts enabled more minority and disadvantaged people to take part in health professions training? Cite any available statistics.

Answer: During the past decade, the Bureau of Health Manpower (BHM) and Office of Health Resources Opportunity (OHRO), and their predecessors, have provided financial assistance to needy students; and awarded grants and contracts to educational and other institutions which are designed to recruit and assist individuals from disadvantaged backgrounds to undertake and complete education and training in the health professions. In addition, efforts have been made, within the framework of the legislation, to address the needs of minorities and the disadvantaged throughout all the Agency's programs. Information has been widely disseminated through printed materials, films, and other media. Regulations have been reviewed and developed in order to make our legislative programs more responsive, and the Office of Health Resources Opportunity was created in 1973 to promote equal access to health careers and services for the disadvantaged.

Preliminary data from an OHRO study evaluating the impact of OHRO and BHM project grants on minority enrollments indicates that the percentage of first-year minority enrollments in supported medical schools, for each year 1972-78, is greater than at non-supported schools. The percentage of minorities enrolled in schools of pharmacy more than doubled from 1972-78 in supported schools as contrasted to non-supported schools where it remained static.

Question: Are such efforts satisfactory?

Answer: The results achieved in the early 1970's were encouraging. Furthermore, although there appears to be a decrease in the applicant pool in medicine, we expect this trend to be reversed as a result of the projects we are now funding at the high school senior and undergraduate level.

DISADVANTAGED ASSISTANCE

Question: What is being done by your agency to redirect health professions training to address the needs of the poor and the underserved?

Answer: The agency addresses the needs of the poor and underserved in several programs designed to improve geographic and specialty distribution. Geographic distribution is addressed in the National Health Service Corp Scholarships, Area Health Education Centers, and Loan Repayment for service in shortage areas. Improved specialty distribution is addressed in programs such as Family Medicine Training, General Practice of Dentistry, Primary Care Internal Medicine and Primary Care Pediatrics, and Specialized Training of Professional Nurses.

Question: What portion of your 1980 budget will be used for this purpose?

Answer: The programs just mentioned make up approximately thirty-nine percent of program funds requested in the 1980 budget.

Question: Is this an increase over the 1979 amount?

Answer: Yes. It is an increase of about six percent compared to the President's revised 1979 budget request.

REORGANIZATION

Question: Dr. Foley, you undertook a fairly extensive reorganization of the Health Resources Administration over the last year. Has this resulted in a reduction, an increase, or a mere reshuffling of personnel? I question somewhat the wisdom of separating the Facilities Compliance and Development function from the Health Planning Bureau. Why was this done? What is it expected to accomplish?

Answer: The new Facilities bureau brings together under one organization the agency's medical facilities programs, health teaching facilities programs, and energy programs. The purpose in concentrating the resources available to these programs and placing them under strong bureau-level leadership is to achieve more effective administration, integration, and coordination of ongoing health facilities financing, compliance, and conversion/closure activities.

Question: Doesn't this dilute the influence of the health planning function?

Answer: No. The Planning bureau continues to administer all of the programs and activities under Title XV, with close interaction and coordination between the Planning bureau and the Facilities bureau on matters of mutual responsibility and concern, such as the development of State Medical Facilities Plans.

Question: How is the reorganization reflected in your 1980 budget request? Please describe any significant changes from last year.

Answer: The only significant change from our budget presentation last year has been to add the Bureau of Health Facilities Financing, Compliance, and Conversion as a separate entity and display the appropriate programs and staffing resources in that activity. The bulk of the bureau's staffing resources were found under the planning and resources development activity last year.

RETREAT

Question: I understand that recently there was an extended meeting of your Agency's top officials in Columbia, Maryland to discuss the future of the Health Resources Administration. What were the results of this meeting?

Answer: The meeting resulted in a clearer idea among the top management within HRA of how the agency would operate during the coming year with an increased role for the Office of Planning, Evaluation, and Legislation in developing policy. Different methods by which communication within the agency could be improved were explored. We decided that a new look at the role of the agency was

in order to see if changing conditions required any new statement of our goals in serving the public.

Question: Is a new mission statement being developed?

Answer: Because of this last consideration, we decided to develop a new statement of purpose which would focus on general policy goals which remain valid even though resource levels may change.

PREPARED STATEMENTS

[The following statements were submitted subsequent to the hearing:]

Statement of the American Association of Colleges of Nursing

The American Association of Colleges of Nursing urgently requests on behalf of its 230 member institutions offering baccalaureate or higher degrees in nursing that you not accept the President's rescission request for nursing funds for fiscal year 1979. Despite the Administration's testimony to the House Appropriations Committee that there is an overabundance of nurses, we have evidence that there is a critical need in every geographical area of the country for nurses prepared at the graduate level to fulfill specialty and primary care roles. In 1976-77, of the total 247,739 students enrolled in the 1,372 basic nursing education programs, only 30 percent (78,461) graduated from baccalaureate programs. In 1975 only 16 percent of employed registered nurses had baccalaureate preparation, and an additional 3.5 percent master's or higher degrees.

According to a Panel of Expert consultants selected for the WICHE (Western Interstate Commission on Higher Education) studies which project future supply and demand for nurses, "Shortages currently exist and are likely to continue long into the future for nurses with advanced preparation in a variety of clinical areas, particularly in community health nursing, as well as in teaching, administration, consultation and research." The panel also predicts that, within the context of expected societal changes, the demand for full-time R.N.s in 1982 will increase from 48 to 104 percent above 1976 figures.

A May 1978 report by the Congressional Budget Office states that "In shortage areas, nurses with less training are more heavily utilized, and many jobs for nurses with more advanced training remain unfilled."

In a survey made by the American Association of Colleges of Nursing, it was found that there are 518 budgeted, unfilled faculty positions in baccalaureate and higher degree schools. The reason: there are simply not enough people adequately prepared at the advanced levels to fill those positions.

The Administration's testimony does not seem to have considered that the eventual enactment of national health insurance will increase the demand for nurses, especially those prepared to function as nurse practitioners, clinical specialists, nursing administrators, and in nursing education and research. In order to be ready to meet the demands of national health insurance, more nurses must be prepared at baccalaureate and advanced preparation levels now.

According to our Nation's "Forward Plan for Health," prevention, teaching and maintenance are major thrusts. Slowly our society seems to be realizing that focusing on disease produces an expensive and inefficient health care system. We need well-educated nurses who can function in a health care delivery system that will focus on disease prevention, teaching and maintenance. Without support for baccalaureate and graduate education for nurses, our society is left to continue to depend upon a very expensive disease-oriented system which requires that any type of care be obtained through very expensive professionals who are specialists in differential diagnosis and treatment of disease. Such a system cannot be afforded and should not be tolerated any longer. Your support of better education and utilization of nurses would allow this country to have a less expensive health care delivery system, place emphasis on health care instead of disease treatment, and move this country closer to equal rights for women.

When Mr. Carter pocket vetoed the NTA extension on November 10, 1978, he promised in his memo of disapproval that "Disapproval of this bill will not cause an abrupt termination of funding of the nurse training programs, since funds are available for FY 1979 under the continuing resolution." Yet on January 31, 1979, the President requested a rescission of 68% of the above funds. Rescission of these funds especially in the areas of advanced training, research, and traineeships would have a disastrous effect on the health care of this country.

If the recommended rescission of $6 million of funds for advanced training stands, 23 graduate programs will lose funds. Loss of these funds for con-

tinuing projects will lead to abrupt termination of faculty. What happens to students? If the funds for research projects and research fellowships are rescinded, 40 nurse researchers will lose support this year, and three graduate programs will lose institutional research training awards. Thirty-three research projects will be terminated abruptly. The loss of funds in traineeships will mean 2,000 already enrolled graduate students will lose tuition support.

In conclusion, we would like to remind you that the new Nurse Training Act calls for a new study to document current and future needs in nursing. It seems indeed premature to accept the Administration's testimony that there is no longer a need for more nurses when the recommended study has not even been started.

STATEMENT OF DR. CAROLYNE DAVIS, COALITION FOR EFFECTIVE NURSE TRAINING

The Coalition for Effective Nurse Training (CENT) is a spontaneous nationwide coalition of individuals who are deeply concerned about the impact of the President's concerted drive to rescind $84 million in the existing 1979 nursing appropriations. A group of over 100 faculty and students from 22 states lobbied extensively with their Congressional delegates on Capitol Hill Monday and Tuesday. They believe that this nation's leading Schools of Nursing are on the threshold of launching a desperately needed as well as cost-effective health care renaissance. Noting that the major thrusts in advanced nurse training and nursing research programs are propelling a quiet revolution in health care delivery, the Coalition spoke out over the impact of the nursing rescisions.

In a meeting yesterday afternoon attended by Congressman Carl Pursell, Dr. Henry Foley, Director of Health Resources Administration and members of the Coalition, Foley admitted that he was fully aware of the fact that the recommended rescisions would cut off funds to programs such as graduate education in gerontology, community health, etc. as soon as April 1 of this year. Institituions that have been hardest hit by these suggested budget rescisions are already notifying faculty of termination of their appointments at the end of this academic year.

When the President pocket vetoed the Nurse Training Act extension, he promised, "Disapproval of this bill will not cause an abrupt termination of funding of nurse training programs since funds are available for fiscal year 1979."

Even with the restoration of some $45 million by the House Appropriations Committee, the impact will be calamitous in most areas of nursing. For example, in advanced nurse training, if the recommended rescisions of $6 million stands, 23 graduate programs will lose funding for continuation of projects as of April 1. These programs include critical areas of study such as oncology (cancer), midwifery, specialists in burn and trauma,

gerontology, community health, and parent-child nursing. Many of these programs meet high priority health needs of this country yet will be wiped out by this precipitous action.

In another vital area, 33 ongoing nursing research projects will be abruptly terminated, since the $1.1 million remaining in nursing research has already been expended. The rescision will effectively negate years of work in nursing research which promises to be of enormous benefit to the nation.

For example, in one state-wide research project in Michigan, the federal government has already spent $1.1 million. Under the rescision, funds would not be available for the final year of this 5-year project. To date, implementation of research findings in this study have resulted in identification of nursing actions that will decrease the incidence of various infections from under 50 percent incidence to zero incidence and decreases the incidence of bed sores from 17 percent to zero in a high risk immobilized patient population. Termination of the project will prevent the implementation of research-based nursing practices which are scheduled for use in numerous hospitals.

Currently, most clinical nursing research studies such as one aimed at the promotion of health care among diabetics, and another demonstrating the utilization of nurses for care of terminally ill children at home, effectively demonstrate cost savings for the health delivery system. Yet these and others like them will be cut off without federal support due to the recommended rescision, as $3.5 million is needed to fund these projects for the rest of this fiscal year.

The Carter administration believes that there is now and will continue to be a surplus of nurses--based upon the assumption that the current nursing enrollment level will continue without federal support. With a reduced level of federal funds for traineeships, scholarships, and other nursing programs, however, it will be impossible for student enrollments to continue at current levels. Additionally, most schools depend upon federal monies for core

support of their educational programs. If these funds are lost, programs may have to close or raise tuition precipitously to cover the necessary increases.

In a Monday afternoon meeting held with Dr. Foley, Congressman Pursell, Dr. Matthew McNulty, President-elect of the National League for Nursing, Dr. Marion Murphy, Executive Secretary of the Association of Colleges of Nursing, and other Coalition members, Dr. Foley suggested that individual schools may have to increase tuition in order to sustain current levels of operation. Further, he suggested that nursing students could seek aid for student support from programs within the Office of Education as well as from National Health Service Corps scholarships. Since only 80 NHSC scholarships are available for all non-medical health students, Coalition members found it difficult to understand how this mechanism will effectively sustain students enrolled in nursing.

Many nurses in advanced training programs will be caught without adequate funds to complete their study. These students have already incurred substantial loans for undergraduate nurse training and find it difficult or impossible to incur more debts.

When the group informed Dr. Foley that the current Wage and Price Guidelines would effectively prohibit institutions from raising tuition to meet the loss of federal funds, he stated that perhaps there could be government action to exclude schools of nursing from wage and price guidelines.

To add to the confusion, President Carter, who vetoed an extension of the Nurse Training Act in November and subsequently requested that most of the appropriations for the current year be rescinded, is expected to send Congress a new Nurse Training bill prior to March 16 House Health subcommittee hearings.

While it is true that since 1968 the overall number of active nurses has grown significantly, it is equally true that hospitals have increased their employment of RN's by 30 percent since 1972 due to the increasingly technological advances in the delivery of acute care services. Recent data (1979) from a

University of Michigan research survey indicate that nursing shortages now exist in 70 percent of the states.

While the $38 million waiting to be restored may not go far in areas such as defense spending, when such monies are distributed for nursing traineeships, fellowships, advanced nurse training, nursing research, special projects and capitation, such funds can guarantee the future of high quality, cost-effective health care for Americans.

e Coalition warns that should Congress follow the President's policy of killing most of the federal programs that are dedicated to training quality nurses, it may unwittingly become an accessory to an extremely short-sighted and dangerous scheme which may yield needless deaths as an impoverished nursing force becomes overwhelmed by patient care needs.

Steering Committee, Coalition for Effective Nurse Training

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REMARKS OF SENATOR MILTON R. YOUNG

Mr. Chairman, last week I had the pleasure of visiting with Dr. Elisabeth Zinser, Dean of the School of Nursing at the University of North Dakota, concerning the $84 million rescission proposed for nursing education.

Dr. Zinser came to UND approximately two years ago and we are extremely fortunate to have someone with her outstanding qualifications coordinating the nursing program in our state. She is highly recognized throughout the country as an excellent nursing educator.

Prior to coming to UND, Dr. Zinser was Assistant to the Vice President for Interprofessional Education for Project Development at the University of Kentucky. Prior to that she was the Coordinator of the Area Health Education Systems and Assistant Professor in the Department of Behavioral Sciences and the College of Medicine at that same university. Presently, she is a Member of the Medical Advisory Committee for the Division of Medicine in the Bureau of Health Manpower at HEW.

I have only highlighted part of Dr. Zinser's outstanding background which makes her judgment on funding of nurse training programs very helpful and important.

Mr. Chairman, I would like to insert in the record of this committee hearing, testimony that Dr. Zinser provided me expressing her concern over the Administration's proposed rescission in nursing funds.

May I point out that Dr. Zinser, like others in the nursing profession, would prefer to see no rescission whatsoever. However, she feels that if there must be a rescission, there are certain areas of nursing education which can best withstand a cut, but rescinding funds in the areas of advanced nurse training, special projects and traineeships will severely handicap this country's ability to maintain an adequate supply of well-trained nurses to meet the increasing demands of health care in the future.

Mr. Chairman, I highly respect and support Dr. Zinser's recommendations.

LETTER FROM DR. ELIZABETH ZINSER

March 6, 1979

The Honorable Milton R. Young
5205 Dirksen Senate Building
Washington, D.C. 20510

Dear Senator Young:

The visit I made to your office last Friday, as well as to the offices of Senator Quentin Burdick, and Representative Mark Andrews, gave me much encouragement regarding the potential for retaining federal support for nursing education.

A recision of funds from the 1979 Nurse Training Act authorizations will have a marked impact upon nursing education, and consequently health care, in North Dakota and the Nation. The purpose of this correspondence is two-fold: (1) to express the position that resource allocation to nursing education for the purpose of facilitating its expanding functions and responsibilities will serve the public well, and (2) to address specific needs for nursing education in North Dakota.

The Nursing Profession:

The Nursing profession is engaged in the most intense expansion of its role, scope, and quality of practice ever seen in its history. This process is based upon the premise that nursing is a major and long-standing resource in the health industry and that furthering the evolution of this available health manpower resource is far less costly to the public than the development of a multitude of new disciplines in an effort to respond to current and future needs in health care. Such needs include control of health care costs; improving accessibility to health care for people regardless of economic status or geographic distance; coordination of an increasingly complex health care team and facility network; the responsible application of technology; and the prevention of disease by such initiatives as consumer education.

Nurses represent a major resource in responding to these concerns. But, to do so, educational programs in nursing must have sufficient resources to build upon its traditional base — to continue to train qualified practitioners of nursing in the traditional roles, but to also prepare nurses who will fulfill expanded functions and responsibilities in hospitals, intermediate and skilled nursing care facilities, physicians offices and multidisciplinary clinics, rehabilitation agencies, hospices, public health agencies, schools and industries.

Health care has become more complex, technical and costly. Further, the public demands and has a right to more from health care practices. The focus of health care has been upon the reduction of mobidity and mortality. The public and health care providers no longer limit their concern to death and disease, but look to the prevention of debilitation, disability, disfunction, depression, distress, disservice, and debts. Indeed, it is the attention to these latter "d's" that represents the promotion of health and quality of life, along with the continuing concern for the more traditional "d's" concerning the prolonging of life and curing of illnesses.

The most outstanding and recent contributions in nursing have been the development of nurse clinicians whose responsibilities and functions serve the public interest for health maintenance, quality of community life, coordination in health care resources, and cost-effective health care practices. The central concern of nurses is to ensure that the human factor remains central in today's increasingly complex and technical health industry.

To meet the challenge of expanded nursing functions and responsibilities for the purposes discussed in the preceding paragraph, nursing education needs federal assistance targeted in particular areas. Initiatives to increase the number of registered nurses remain, but are of less concern than initiatives to improve the quality and function of nursing practice. The priority needs are as follows: (1) to focus institutional and student assistance upon the basic preparation of professional nurses with the advanced education required to assume expanded responsibilities, such as baccalaureate level preparation; (2) to focus support on the more underserved areas, principally rural and inner city, since progress has been retarded by greater fiscal constraints and the population base; and, most important, (3) to concentrate federal support upon the development of advanced nurse training programs and student traineeships at the graduate level for the preparation of the profession's leadership in four categories: (a) advanced nurse clinicians and practitioners, (b) nurse educators teaching in schools of nursing, (c) nursing supervisors, managers, and administrators, and (d) nursing researchers. Indeed, as in any profession, the quality of nursing practice is dependent upon the effectiveness of the profession's leadership. It is this area that has received the least attention in previous years and requires the greatest support now.

Nursing Education in North Dakota:

Nursing education in North Dakota is making outstanding strides in a number of areas. All of our nursing schools have joined together, with representatives of nursing service and professional organizations, in the form of the North Dakota Nursing Education Consortium. This Consortium serves to develop a statewide plan for nursing education, to identify common needs, to share available resources, to avoid unnecessary duplication, and to promote projects which will bring North Dakota into the forefront as a leader in rural primary care nursing education. This entails four principle objectives: (1) to improve accessibility to graduate nursing education by developing a masters degree program at the University of North Dakota College of Nursing; (2) to develop a shared statewide network for continuing nursing education; (3) to improve career mobility for nurses as they move from diploma and associate degree programs to baccalaureate degree preparation; and (4) to develop clinical primary care experiences for our nursing students in the more rural communities as an effort to encourage better geographic distribution in our state. North Dakota is depending upon available federal support in the category of "Special Projects" to develop these activities in the coming years.

There is certainly not a "glut" of nurses in North Dakota. Supply and demand is evident. First, the UND College of Nursing has far more qualified applicants than can be admitted to the program based on current resources. Second, we have seen a trend toward increasing proportion of men entering the profession (nearly 10% now at UND College of Nursing). Third, a recent survey of our graduates found 95% employed and 80% located in the three Health Systems Agency areas serving our state. Thus, continuing support for our institutions and students will serve well the needs in health care for North Dakota.

The greatest need in nursing education within North Dakota is the development of a graduate program in nursing at the University of North Dakota College of Nursing. This aim has been endorsed by the North Dakota Nursing Education Consortium, the North Dakota State Nurses' Association, and the North Dakota State Department of Health. The immediate and critical consequences of not developing graduate education for our nurse leadership is the almost certain loss of accreditation in our schools of nursing. The National League for Nursing expectations include as paramount the employment of nurse faculty with earned masters or doctoral preparation in nursing. This is a reasonable expectation since the mission of undergraduate education is to prepare basic nurse clinicians but not nurse educators, clinical nurse practitioners or specialists, or administrators. For these responsibilities, graduate education is imperative.

Graduate level preparation of nurse faculty has been achieved in a majority of states, but some lag behind and thus are in jeopardy of loosing accreditation. If accreditation were lost, our programs would experience a drop in enrollment, difficulty in faculty recruitment, and become less competative for sources of support; and our graduates would have difficulty gaining admission to graduate programs and acquiring certain job opportunities such as public health positions.

North Dakota ranks lowest in the United States as to the proportion of nurse faculty with masters degree preparation (33%). The UND College of Nursing has just completed a feasibility study for development of a graduate program. We have identified 460 eligible nurses who indicate a serious intent to pursue their masters degree in nursing if a program were to come available at UND. The job market evidenced demand for masters prepared nurses with the identification of 110 current positions in schools of nursing and 85 current positions in nursing service units upon a sampling interview of hospitals and public health agencies. The need is evident.

The University of North Dakota College of Nursing intends to actively pursue the development of a graduate nursing program. Initial support in development will be sought from the "Advanced Nurse Training" category in the Nurse Training Act. However, if there is a recision of any amount in this category, such support will not be available when we make application this July. There are $9 million currently commited to continuation applications in Advanced Nurse Training, leaving $3 million for competing new applications such as ours. Thus, we urge that you support the retention of the full amount ($12 million) in "Advance Nurse Training" and in "Traineeships".

In summary, I will reinforce the specific aim that we hope you will support on behalf of the Nurse Training Act, particularly as it relates to North Dakota's needs:

(1) That, if a recision is necessary in a time of increased fiscal restraint, that any recision of funds from Nurse Training Act authorizations be limited to $20 million, thus leaving at least $102 million in the Nurse Training Act. This would be comparable to proportional recisions proposed in other health education programs, and;

(2) That the full authorized amounts be retained in the following priority categories:

(a) Advanced Nurse Training
(b) Special Projects
(c) Traineeships

(3) That relatively little be cut from the other areas of priority; totaling a reduction of not more that $20 million.

Nurses and nursing schools in North Dakota recognize and appreciate the support you have consistently provided to nursing education. We hope that this statement of concern and factual information will be helpful to you in your current efforts to oppose, or at least limit the degree of, a recision of federal support to nursing education.

Thank you for your continuing attention and actions toward the improvement of nursing education and thus, health care, for North Dakota.

Respectfully,

Elisabeth Zinser

Elisabeth Zinser, R.N., M.S., Ph.D.
Dean, College of Nursing

SUBCOMMITTEE RECESS

Senator BURDICK. The subcommittee will stand in recess until 10 tomorrow morning.

[Whereupon, at 3:30 p.m., Tuesday, March 6, the subcommittee was recessed, to reconvene at 10 a.m., March 7.]

DEPARTMENTS OF LABOR AND HEALTH, EDUCATION, AND WELFARE AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 1980

WEDNESDAY, MARCH 7, 1979

U.S. SENATE,
SUBCOMMITTEE ON THE COMMITTEE ON APPROPRIATIONS,
Washington, D.C.

The subcommittee met at 10 a.m. in room S-128, the Capitol, Senators Warren G. Magnuson and Birch Bayh presiding.

Present: Senators Magnuson and Bayh.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

STATEMENT OF DR. JULIUS RICHMOND, ASSISTANT SECRETARY FOR HEALTH

BUDGET REQUESTS

Chairman MAGNUSON. The subcommittee will come to order.

This morning, Dr. Julius Richmond, the Assistant Secretary for Health is with us to give us an overview of the Public Health Service's 1980 budget request of $7.8 billion. We will also be discussing the $260.6 million request for programs within the Office of the Assistant Secretary for Health.

Dr. Richmond, I understand that you have several new programs within the purview of your office this year. The committee is interested in learning about these new initiatives. You just go ahead with your opening statement and you can identify the people with you.

INTRODUCTION OF ASSOCIATES

Dr. RICHMOND. It's a pleasure to be with you and to have my colleagues with me. On my right I have Mr. Charles Miller who is Deputy Assistant Secretary for Health Operations; and on his right—he shifted positions since his last appearance before this committee.

Chairman MAGNUSON. I know he has shifted around quite a bit.

Dr. RICHMOND. Mrs. Ruth Hanft, who is Acting Deputy Assistant Secretary for Health Research Statistics and Technology; and on her right, Mr. Howard Viet, who is Director of Health Maintenance Organizations; and on his right is Miss Ellen Wormser, who is Director of the Budget, Office of the Secretary; and on my left, Dr. James Mongan, who is Acting Assistant Secretary for Health Planning and Evaluation; and on his left, Dr. Lulu M. Nix, Director of the Office of Adolescent Pregnancy Programs; and on her

left, Dr. Michael McGinnis, Acting Deputy Assistant Secretary for Disease Prevention and Health Promotion.

WARREN G. MAGNUSON HEALTH SCIENCES CENTER

Chairman MAGNUSON. We are glad to have you all here.

Dr. RICHMOND. Mr. Chairman, if I might interject in the hearing room of this subcommittee how deeply pleased I am to have the opportunity to testify before you again and in these chambers to interject a note. The note is that I had an unusual opportunity last November 3d to go to Seattle and admire the great good judgment of the people of the State of Washington in renaming their health science centers the Warren G. Magnuson Health Sciences Center of the University of Washington.

Chairman MAGNUSON. We were glad to have you there. You made a great contribution to the affair. You should have stayed the next day. We had a good football game.

Dr. RICHMOND. I heard about the halftime ceremony spelling out Maggie.

I think, Mr. Chairman, more seriously, it seemed to me that it did provide an opportunity to recognize the long term contributions that you have made not alone to the health of the people of the State of Washington but to the Nation and to the world. One could comment on the imagination with which you pursued the legislation for cancer control and research in cancer which led to many of the develoments of our great National Institutes of Health, and one could talk about many of your efforts in prevention, including automotive and water safety. One could talk about your contributions in so many ways to health services, particularly the imagination with which the National Health Service Corps was developed. So that I could go on and on. It's been a remarkable record and I was very pleased to participate in that ceremony.

IMPROVED HEALTH STATUS

It was in that context, Mr. Chairman, that I thought it would be well to discuss this morning the progress which has taken place in the past several decades in the improvement of the health of our Nation, the health of our people, and then to look toward the future in terms of priorities to continue the improvement of the health of our citizens.

Today the health of this Nation's citizens has never been better. Life expectancy has increased to 73.2 years, an increase of 2.7 years over the past decade. This contrasts with an increase of 1 year in the previous decade. Since 1950, the infant mortality rate has been reduced by more than one-half and now stands at 14 deaths per 1,000 live births. Over the past 25 years the age adjusted death rate has decreased 25 percent. And, while heart disease continues to be the leading cause of death, between 1960 and 1976 there has been a 9-percent decrease in the death rate from heart disease.

The health of America's children is better now than ever before. Most of the common infectious diseases of children have all but disappeared. The eradication of small pox throughout the world has been a remarkable achievement. We have today a therapeutic

armamentarium that would have been regarded as science fiction during my medical school days.

AREAS WHICH NEED IMPROVEMENT

Yes, despite these noteworthy accomplishments there is still much that can and should be done:

Significant differences still exist between blacks and whites in infant mortality and life expectancy rates. In 1976 the black infant mortality rate was still almost twice as high as the white infant mortality rate. Death rates continue to be higher for black people than for white people.

As recently as 1976 a substantial number of children were not protected from preventable childhood diseases. To deal with this problem, the Secretary launched an immunization initiative in early 1977. The results thus far indicate that it is possible to correct this problem.

Forty-two percent of men and 32 percent of women still smoke, despite overwhelming evidence of the health risks associated with smoking.

Heart disease and cancer continue to be the two leading causes of death, accounting for nearly 60 percent of all deaths.

Mental disorders affect an estimated 15 percent of the U.S. population in any given year—almost 32 million people in 1975.

An estimated 10 million people are reported as having a significant alcohol related problem. The overall increase in the drinking among youth is of particular concern. In 1974 more than a quarter of 12- to 13-year-old male students and two-thirds of all 18- to 20-year-old male high school students had at least one drink once a week, two drinks three times a month, or five drinks once a month.

The Federal priorities I would like to outline for you now represent an attempt to respond to these problems. The majority of our requested increases in the 1980 budget are related to these priorities.

INFANT MORTALITY RATE

Chairman MAGNUSON. Before we go into that, you mentioned that the infant mortality rate has been reduced by more than one-half. We still are way down on the whole, aren't we, in comparison to the infant mortality rates in other countries?

Dr. RICHMOND. Yes, Mr. Chairman.

Chairman MAGNUSON. Not the underdeveloped countries but the other countries.

Dr. RICHMOND. Yes. I think, Mr. Chairman, it's appropriate to point out that we rank approximately 12th among the countries of the world and the Scandanavian countries in particular have brought their rates down to what some of us thought were impossibly low levels relatively few years ago. Sweden even now is below a rate of 9 in contrast to our 14; Denmark, Japan, Holland, and a number of Western European countries are considerably below ours. So that we have something to aspire to.

Chairman MAGNUSON. I have always been concerned about the U.S. ratio compared to that in other countries and what we might

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do about it. I suppose it's because the Scandanavian countries don't have as many births per population as we have.

Dr. RICHMOND. Well, we are approaching their birth rates in recent years. Our rates have come down. I think, Mr. Chairman, this relates significantly to the fact that we are still not doing as well with our low-income population, particularly of minority group background, and we are concentrating on this at the present time in terms of trying to improve our efforts to reach those populations. We feel quite certain that if we get prenatal care to them in a timely fashion, if all the perinatal services are available to them, and if we also during the course of the first year could do a better job in providing support systems, particularly to teenage mothers, mortality rates would be reduced. Mr. Chairman, we do have a problem in that a significant number of the births in this country, approximately one-fifth, are to mothers who are still in their teens. That is not a great hazard for mothers who are in their upper teens, but we have about 30,000 pregnancies to girls under 15 years of age. There are about 13,000 births in that group which is a group at extremely high risk and we are trying to solve that problem.

LIFE EXPECTANCY

Chairman MAGNUSON. The life expectancy in the United States has increased to 73.2 years, an increase of almost 3 years over the past decade. How does that compare with the decade before that?

Dr. RICHMOND. Well, the decade before we increased by 1 year and the last decade by 2.7 years, almost 3 years. And we think to a considerable extent this is due to our continuing improvement in child health but also what we have begun to see, Mr. Chairman, is a significant drop in the mortality from cardiacs and that's been largely in the past decade.

Chairman MAGNUSON. Over the past 30 years, in the postwar period, World War II period, we have increased it quite a bit, haven't we?

Dr. RICHMOND. Oh, yes. We have, Mr. Chairman, increased from—if we take the turn of the century, the length of life was 47.3 years, and coming up to the 73.2 is quite a shift.

Chairman MAGNUSON. I hope the life insurance companies know of that. All right. I wanted to get those figures on the record because the mortality of the Americans has gone up considerably. I'm glad to get the exact figures over the past 30 years.

INFANT MORTALITY RATE FOR BLACKS

Now the black infant mortality rate is high. Is that because of the unavailability of services, prenatal services, or what? I mean, we have in our health programs always had the thrust of aid to minorities and ghettos or even rural now where we are trying to make more services available. Is that because people don't take advantage of the services or because we don't have enough? Which is it?

Ms. HANFT. It's in large measure the latter. We don't have enough. We have some 50 million people who live in what we call underserved areas.

Chairman MAGNUSON. And that probably accounts for it because going beyond the black infant mortality rates the whites are usually in places where there are better facilities.

Dr. RICHMOND. Well, I think that's true to a considerable extent, however, the white population that is of low income, their rates are higher as well. So we do need to concentrate on those of low income.

Chairman MAGNUSON. Well, would the cost enter into this?

Dr. RICHMOND. Theoretically, those of low income now have access to title 19 medicaid, but I think there, Mr. Chairman, particularly in the low-income areas, the reimbursement situation has not been favorable for physicians in the private sector to participate. So we are examining how we may turn that problem around as well.

Chairman MAGNUSON. Well, on the same basis, isn't it true that even though we may theoretically have the available services, under the medicaid program some of the medical profession are not taking the patients? Isn't that true?

Dr. RICHMOND. Yes.

Chairman MAGNUSON. They don't deny them once they get there, but they don't go out and try to attract patients, and this would have a great effect on this mortality. So we have a long ways to go on that, don't we?

Dr. RICHMOND. Yes, sir; one of the issues that you're touching on is that related to accessibility. That is, many times the services are not readily accessible and, of course, the National Health Service Corps, which you were influential in developing, is one method that we are utilizing to try to get professional people into the areas of greater need, particularly where it's extremely difficult geographically.

RURAL HEALTH

Chairman MAGNUSON. What about the rural areas? Is the problem the lack of availability there?

Ms. HANFT. Yes; it's both urban and rural.

MENTAL DISORDERS

Chairman MAGNUSON. Now when you talk about mental disorders affecting at least 15 percent of the population, what do you mean by mental disorders? That's a broad term. We know that heart disease and cancer are the leading causes of death and that we have made significant progress in heart disease. I was a little bit disturbed by this recent report on cancer, but now we have mental disorders. What do you mean by mental disorders? There are certain obvious mental disorders, but how far do you go when you categorize somebody as having a mental disorder?

Dr. RICHMOND. The data that we are drawing on are those of the President's Commission on Mental Health. In this category we would include certainly the 1½ to 2 million people who are chronically and very seriously mentally ill, the people who are in and out of our State hospitals.

Chairman MAGNUSON. Certain laymen can tell?

Dr. RICHMOND. Yes. But we are impressed, Mr. Chairman, with the fact that health practitioners report anywhere from 40 to 60 percent of people in their practices come to them because they have some emotional problem rather than a physical problem, and that group falls within a spectrum—some are more disturbed and ultimately require psychiatric referral, but a great many of those people can be taken care of in the general health sector and that bespeaks the need, Mr. Chairman. One of the recommendations of the report of the President's Commission on Mental Health is that we must have greater linkage between the mental health system and the health care system. In other words, we need to provide better education, for example, for the primary care physicians to deal with those problems.

FUNDING FOR COMMUNITY MENTAL HEALTH CENTERS

Chairman MAGNUSON. That flies in the face of the dilemma we have here, when the budget itself is advocating the phasing out of all community mental health centers. I don't mean this budget. I mean every budget in the last 4 or 5 years wants to phase out the community mental health centers, the Federal participation, and there are no new ones on the agenda at all in this budget. But that's a matter we will have to decide, I guess, in this committee.

Dr. RICHMOND. Well, Mr. Chairman, we are proposing legislation for a Mental Health Services Act which we think would accomplish precisely the objectives originally intended through the community mental health centers program.

We think, however, that mental health services throughout the country have developed sufficiently so that we can introduce more flexibility for communities at the local level and try to tailor the mental health services programs at the local level and not specify all of the formal requirements, the 12 requirements, that go into the development of a community mental health center.

So we are proposing further mental health services at the local level.

Mr. MILLER. There's money in the President's budget, almost $100 million, to fund that, Mr. Chairman.

Chairman MAGNUSON. But in your budget at the end of the period it would be all phased out.

Mr. MILLER. But the net amount in the budget for community mental health is higher in fiscal year 1980 than it is in 1979, even though there are no new starts for community mental health centers. There's about a $60 million net addition for community health services.

Chairman MAGNUSON. But in the end you get rid of them, get rid of the budget support in the end. Well, I'm just advised here that there's $321 million in 1979 and $248 million in this year's budget in community programs.

Ms. HANFT. The legislation itself that now exists calls for a limited period of Federal support.

PENDING LEGISLATION

Chairman MAGNUSON. Everybody comes down here and talks about legislation that's pending, that is going to be introduced, and

we have nothing to do with that. We can't appropriate money on proposed legislation.

Ms. HANFT. But the current legislation calls for the phaseout of the centers after a certain number of years.

Chairman MAGNUSON. I know, and the administration is following that. It flies in the face of the fact that mental disorders as you people have determined from your survey have gone up. There are more of them. This figure of 15 percent more is much higher than I thought it would be.

Ms. HANFT. Well, that includes a broad spectrum of people.

Chairman MAGNUSON. I know. Everybody has emotional problems sooner or later in their life and you're considered to be abnormal if you don't.

Dr. RICHMOND. That's for sure.

Chairman MAGNUSON. You and I have emotional problems every day in the week. All right. I just want to get those general questions in before we start on your priorities.

Senator Bayh, do you have anything?

NEW STARTS FOR COMMUNITY MENTAL HEALTH CENTERS

Senator BAYH. Mr. Chairman, I don't want to interrupt. However, I thought it might be appropriate to ask a question in the area of community mental health. Last year I strongly supported an appropriation of $30 million for first year growth for community mental health centers. Two approved but unfunded centers happen to be in my State, Richmond and Anderson, and the best information I have is that that money isn't being spent. I would like to know what's happening to that $30 million? How is that going to fit in with the new program?

Ms. WORMSER. The money for new starts that was appropriated by the Congress has been apportioned in the fourth quarter of this year. As Ruth Hanft mentioned, there is a proposal pending for new mental health legislation that would provide different kinds of services targeted at the same kind of problems in the community. It was the intent of the budget to use that $30 million for those new kind of services in communities once the mental health legislation is passed. If it doesn't get through, the money would be spent on the traditional mental health centers.

Senator BAYH. We had the appropriations and the authorization. We had a timing problem last year which created a little bit of a problem, but I find it difficult to see how the Administration can propose new legislation and totally ignore the will of Congress in authorizing and appropriating $30 million to fulfill specific purposes under the old legislation.

Mr. MILLER. But, Senator, Ms. Wormser's final answer was I think that we want the Congress to have an opportunity to consider the legislation. If the timing problem is too great and the new legislation is not authorized, we will spend the money. We are not proposing it be rescinded.

Senator BAYH. But you see, I'm sitting here trying to explain to my constituents how something that happened last year is going to be put off until the fourth quarter of this year. How do I explain that to them?

Mr. MILLER. That's a very short delay, Mr. Chairman, in order to get geared up, and it would normally be about the fourth quarter——

Senator BAYH. They have already been approved and we can sit here and say that's rather short, but the people out there who have been working on it for a long period of time have great expectations, and they have frustrations when they don't get funded in a timely fashion. Finally when we get them authorized, we appropriate $30 million, which their Senator had something to do with, and then suddenly the money is not being spent. I thought there might be some easier explanation than to say, "We may not do it at all; we're just going to put it off and see if the new program takes the place of the old program." How can you do that? It seems to me we're getting into a direct confrontation here, which I don't think any of us really want.

Chairman MAGNUSON. We've got a law on the books. There are new programs proposed in every agency and you've got to go ahead and do what the Congress has suggested you do for the given year. If a new program shows up, that's another matter.

Mr. MILLER. But we do need to recognize that the difference between when the money is obligated this year and last is maybe 3 to 6 months at the most.

Chairman MAGNUSON. Why hold it up for 6 months?

Mr. MILLER. To simply give the Congress an opportunity to consider spending it a different way.

Chairman MAGNUSON. Congress didn't want that opportunity. They told you last year what they wanted and that's it. Next year you come up with a supplemental or new legislation. I'm getting a little perturbed about all the witnesses that come up here—and HEW in particular—and they're all talking about new legislation. We're going to mark this bill up in about 60 days. We can't come up with new legislation. Do you want me to give you a little advice? It ain't going to happen before we mark this bill up.

Senator BAYH. Mr. Chairman, I've heard of optimistic talk in my life, but I've got to say that to suggest we're going to pass a new program through both Houses of Congress, between 3 and 6 months is close to impossible. I don't recall that ever happening, particularly if the program has any substance to it, and I assume it will have substance.

But in the meantime, we appropriated money last year. The new program to be funded would be this year and the appropriations bill is going to pass significantly before that new program is going to pass, if indeed it does pass. In the meantime, we have that money we passed last year for 28 centers that have been approved for funding. Although two of them happen to be in my State, I'm also concerned about those that have been approved in other States.

What do we have to do to get the wishes of Congress considered in this matter? We're talking about as long as a year's delay. If you are holding this off for the passage of the new program—let's assume that it passes—we were passing programs here at 11:30 at night or 6 o'clock on Sunday on the last day of the session, and if we're talking about a comprehensive new program where we may have some differences between the Congress and the administra-

tion it could go down to the last part of the session. Now that's as much as a year. How do you rationalize that?

RESCISSION

Chairman MAGNUSON. If you aren't going to use it under the present law, you ought to send up a rescission.

Mr. MILLER. Well, we will not allow the length of time that the money is available to expire without spending the money. We are not requesting a rescission.

Chairman MAGNUSON. This is the purpose of Congress, to control the expenditure of money which is rightfully ours, and we said if you don't want to spend it don't hold it, send up a rescission, and you're doing pretty well with the rescissions over there. The House just worked on one yesterday. Califano had charts up here on Monday and they all talk about appropriations subject to legislation. Well, there isn't going to be any significant health legislation passed between now and the time we pass the appropriations bills. Everybody knows that. It would be impossible because this year we're working toward a deadline. We started our hearings even before the House in some cases.

Senator BAYH. We didn't go off here on a toot of our own establishing a new program. May I ask, Mr. Chairman, what authority does HEW have for taking money that has been specified by Congress for a particular authorized ongoing program for community mental health services and spending these funds for something entirely different? And this was a joint effort with the administration——

Mr. MILLER. I think there's a legitimate controversy on that, Senator. If it had not been what we regarded as the normal obligating pattern in the year we should have sent up a deferment and that would have been our authorization. We believe that the money will go out at substantially the same rate it normally does and it doesn't require deferment, but that's a legitimate argument.

Chairman MAGNUSON. I should change the term. I meant deferral rather than rescission.

Mr. MILLER. Well, I know that's a close call, Mr. Chairman.

PRIORITIES

Chairman MAGNUSON. All right. Go ahead, Doctor, with your priorities.

Dr. RICHMOND. Priorities, Mr. Chairman, relate to: First, the prevention of disease and the promotion of health; second, the extension of health services to the unserved and underserved through reforms of the health care system; and, third, the improvement of mental health and alcoholism programs.

Our prevention efforts call for the following:

First, to continue efforts insuring that at least 90 percent of all children are immunized against the major childhood diseases. We anticipate now that we can eliminate measles in the United States by 1982.

IMMUNIZATION

Chairman MAGNUSON. All right. Now on that item, in the 1980 request in the immunization efforts there's a reduction from the 1979 amount and our figures indicate there are, of the 52 million children under 14 years of age or younger, 20 million who have not been adequately immunized against childhood diseases. Is that correct or is that figure too high?

Dr. RICHMOND. I think that figure is high. Since the development of the initiative certinly among the school age population, more than half the States are now reporting over 90 percent of the children fully immunized.

Chairman MAGNUSON. We got these figures from the Center for Disease Control.

Dr. RICHMOND. The figure that you have, Mr. Chairman, what was it?

Chairman MAGNUSON. We've got 52 million children 14 years or younger, approximately 20 million have not been adequately immunized against childhood diseases.

Dr. RICHMOND. Well, I think that is a definitional problem.

Chairman MAGNUSON. Of course, that might be specific diseases.

Dr. RICHMOND. Yes.

Chairman MAGNUSON. For instance, they say that 18 million are inadequately immunized against polio, 14 million against rubella, 12 million against measles, and 13 million against DPT.

Dr. RICHMOND. Yes. I think that is the problem, Mr. Chairman. I might ask Dr. McGinnis if he might want to comment on those figures.

Chairman MAGNUSON. Well, you say you will continue efforts to immunize all the children. That's the goal. That's a goal you have?

Dr. RICHMOND. Yes.

Chairman MAGNUSON. And yet there's a reduction from the 1979 amount.

Dr. RICHMOND. Well, I would like to have Dr. McGinnis make some comments. Before that, what I would like to explain about that reduction is that we did need funds to catch up on the backlog of unimmunized children and we think we have done a considerable catchup job in 1979. The funds that we are requesting in 1980 are adequate to maintain the momentum to complete the job, Mr. Chairman, and that's the reason.

Dr. MCGINNIS. Just a brief elaboration. I think the figures you have before you on the 20 million unimmunized children reflect a situation that no longer exists. Those are old figures. We in fact have made considerable strides in immunization and I think there are two elements we have to consider. Most importantly, one is that disease incidence is really at an all-time low and this is an epidemic year. Measles, for example, runs in trends and this is the year in which we would expect measles to be at a peak and in fact we are seeing that it's at an all-time low. So we can anticipate that our program has had considerable success.

In addition, the figure that you have of 20 million is based on the annual U.S. Immunization Survey which relies on parental recall. We think that such historical surveys present certain problems in

the collection of accurate data, and we are working to improve the methods available for tracking the actual immunization level.

The bottom line, however, is that disease incidence is at an all-time low and we think we have been very successful in reducing it through the initiative.

IMMUNIZATION DATA

Chairman MAGNUSON. Do I understand that what you're trying to do is concentrate—this being a measles year—you concentrate on immunizing children against measles only?

Dr. MCGINNIS. No. Our program is across the board, directed at all diseases.

Chairman MAGNUSON. It doesn't pick out one?

Dr. MCGINNIS. Absolutely not. It's directed at the seven major childhood diseases.

Chairman MAGNUSON. How do they get those figures that are so widely divergent—18 million against polio and 13 million——

Mr. LIERMAN. Is that 18 million right for polio?

Dr. MCGINNIS. I believe those are old figures. We'll have to submit for the record an updated figure.

[The information follows:]

The immunization initiative was based upon data from the 1976 U.S. Immunization Survey (USIS). These data indicated that approximately 20 million children age 14 and younger were inadequately immunized against one or more of the common childhood vaccine preventable diseases. Approximately 18 million of these were estimated to be inadequately protected against polio (less than three doses). Data from the 1978 USIS indicate that 17.6 million children are still inadequately immunized against polio. The number of children who had received no doses of polio decreased from 4.5 million in 1976 to 3.8 million in 1978. However, because of the imprecise nature of historical surveys, the USIS (a national probability sample conducted each September) probably does not reflect the true immunization status since these data are based on parental recall rather than medical records. To more accurately reflect immunization status in the future, standardized immunization data systems are being implemented throughout the Nation beginning this fiscal year (1979) to document immunization levels at the time of entry into school.

EFFECTS OF IMMUNIZATION

Chairman MAGNUSON. Bring us up to date because this is a little bit confusing. I know what you're trying to do. You are trying to achieve that goal, but when we find that the budget is down from last year we wonder how you're going to do it.

Dr. MCGINNIS. Dr. Richmond's point I think is right on the target. We have made great gains and therefore we can move into a consolidation phase at a lower level.

Dr. RICHMOND. For a disease like measles, Mr. Chairman, it has been occurring largely at the school age level. It hasn't been occurring in the younger children and the fact that we have succeeded apparently in immunizing over 90 percent of the school age children in many of the States in the country seems to be having its impact and that is that measles is at the lowest point in history for the past 5 weeks consecutively. We have never had lower numbers of cases of measles and, as Dr. McGinnis points out, this should be the measles season, so it's a very encouraging trend and we are examining proposals which could lead to the elimination of measles by the year 1982.

Senator BAYH. As you know, I have been very interested in this issue and the Chairman and I put extra money in the budget for immunization. What is our goal? Are we looking to obtain 100

percent? Are we trying to see that every child in America isn't going to contact infantile paralysis, or measles, or the others?

Dr. RICHMOND. Senator Bayh, I think we can say if we immunize 90 percent of the children fully that we probably are in a reasonably safe situation in terms of any outbreaks of these diseases. It doesn't mean that an occasional individual child wouldn't be vulnerable and we would, of course, desire to have 100 percent of our childhood population fully immunized. We do recognize, however, that we may be able to complete the job, for example, to eliminate measles, by getting the rate up to 90 percent and not having to necessarily get to the 100 percent, even though that would remain a goal.

Senator BAYH. The 90 percent is a lot better than where we have been and I compliment you. I certainly think things are moving much more aggressively and positively than when we started worrying about this 3 or 4 years ago. I feel we ought to try to convince every mother and father that their child ought to take advantage of these things. There's still significant numbers of children that aren't immunized for infantile paralysis and I just wonder if we are trying to put the program together so we try to reach every child and every parent?

Dr. RICHMOND. Yes, indeed. That is clearly the objective but for practical purposes we have virtually no polio in the country. We had seven cases reported last year, the lowest in history, and still would prefer that to be zero, and we think we can probably achieve that.

Senator BAYH. Don't we have several million children now that have not been immunized?

Dr. RICHMOND. Immunized, but the number of cases in the country are down to seven in the last year for which we have records. So we keep moving downward and we think our initiative which started about 18 months ago has really had a major impact. Certainly with measles it seems to be very clear.

SUCCESS OF CHILDHOOD IMMUNIZATION PROGRAM

Senator BAYH. You are all to be complimented in getting that number down to seven, but if the immunization program results in several million year after year that aren't immunized, then we're setting ourselves up for an outbreak? I think we can tend to be complacent—the school population and the parent population and maybe the public health population—if we said, well, we only had seven in the country.

Mr. Chairman, would it be appropriate to ask—not here—but that you let us know for the record just what has to be done in order to get the 100-percent mark. Where are we falling down? I'm sure it isn't 100 percent in every community. Probably in some communities they have 100 percent and in some maybe they have only 50 percent. Could you give us a breakdown so we could help you plug up those holes?

Dr. RICHMOND. Yes; we certainly can. Your objectives are precisely what we aspire for.

[The information follows:]

Although the U.S. Immunization Survey cannot provide precise immunization level data by project area, other data indicate that much progress has been made.

Since the beginning of the initiative, 23 States have strengthened and updated their school immunization laws. A total of 31 States now enforce their requirements that children entering school be fully immunized. Sixteen States have completed a review of the immunization status of every student from kindergarten through the 12th grade in all schools both public and private. An additional 21 States are in the process of completing this task. It is estimated that final reports from the fall of 1978 will show that 32 States have achieved immunization levels of 90 percent against the six major childhood diseases, excluding mumps, for children entering school; five of these States have reported that more than 95 percent of their entering students are immunized against all seven diseases. (Table below.) We expect school entry surveys which will be carried out in the fall of 1979 to show 90 percent or better of children entering school will have completed all recommended immunizations.

1978/79 School Enterers Surveys

Status as of 2/16/79

		Complete	DTP	Polio	Measles	Rubella	Mumps	ALL
I	Connecticut	Yes	96	96	94	92	71	-
	Maine	Data on K and K-6 inventory not tabulated						
	Massachusetts	Yes	98	98	98	95	95	-
	New Hampshire	Yes	94	94	96	96	93	-
	Rhode Island	Yes	93	93	93	92	52	-
	Vermont *	See explanation						
II	New Jersey	Yes	97.7	97.4	99.1	98.9	No	96.5
	New York State	Yes	Not available yet					
	New York City	Yes	1st survey shows 60 percent adequate and 7 percent in process					
	Puerto Rico							
	Virgin Islands	Not done	yet					
III	Delaware 3/1							
	D.C. public	Yes	97	95	98	97	95	86
	Maryland							
	Pennsylvania	Yes	98	94	94	93	-	-
	Allegheny Cty	Yes	94	93	93	93	-	-
	Philadelphia	Yes	84	83	83	81	-	-
	Virginia	Yes	94	94	95	95	-	-
	West Virginia	Yes	98	97	98	98	-	-
IV	Alabama	Yes						96.2
	Florida	Yes						93.1
	Georgia		Available March					
	Kentucky	Yes						89.2
	Mississippi		92	92	92	92	-	-
	North Carolina	Yes						96.5
	South Carolina	Yes	Available ASAP					
	Tennessee	Data not available because of new law						
V	Illinois	Yes	Available by March 31					
	Chicago	Yes	included in the State					
	Indiana	Yes	Available by March 31					
	Marion Cty	Yes	(included in State)					
	Michigan	Yes	Available by March 31					
	Minnesota	Yes	Available by March 31					
	Ohio (Prelim.)	Yes	97.5	97.1	97.7	97.8	-	-
	Wisconsin	Yes	Available by March 31					
VI	Arkansas	Yes	96	96	97	97	-	95
	Louisiana	Yes	93	93	95	92	-	-
	New Mexico	Yes	98	98	98	98	-	-
	Oklahoma	Yes	96	94	96	96	-	-
	Texas	Yes	97	97	98	98	-	-
	Houston	Included in State						
	San Antonio	Included in State						
VII	Iowa	Yes	94.4	94.8	95.7	95.9	86.2	-
	Kansas(Prelim.)	Yes	86 (4+)	88	90	90	85	80
	Missouri	Yes	96.5	96.7	94.7	92.8	68.7	-
	Nebraska	Yes	97.4	97.0	96.7	96.3	90.2	-
VIII	Colorado	Yes						73.1
	Montana	No	Not completed					
	North Dakota	Yes	Has been sent in					
	South Dakota	No						
	Utah	Yes	96.1	97.1	98.3	98.2	97	86.1
	Wyoming	Yes	89	88	90	89	86	76
IX	American Samoa							
	Arizona	Yes	94	92	90	88	68	-
	California	Due March 1, 1979						
	Guam	Yes	92	91	90	90	86	
	Hawaii	Yes	99	99	99	99	89	-
	Nevada							
	Trust Territory							
X	Alaska	No	Completed by March 31, 1979					
	Idaho	Yes						67 (4+)
	Oregon	Yes	91.8	93.2	97.5	96.5	85.1	-
	Washington	Complete by 2/20/79						

*Vermont - Typical survey not completed this year due to autonomy of towns and their use of different methods. Preliminary data on K-12 inventory by 3/15

Chairman MAGNUSON. You had $50 million in 1979 and that included a $20 million supplemental; is that correct?

Mr. MILLER. That's correct.

Chairman MAGNUSON. And the administration is asking for $33 million in 1980. Now how is that $33 million distributed? Give us a map of how you distribute it. What do you do? How does it work? Does it work through the schools mainly?

Dr. MCGINNIS. It's distributed through 63 projects across the country and those immunization projects represent one project in every State plus one in some of the major metropolitan areas. Those projects, in turn, use the moneys to operate information programs as well as some immunization public health clinics.

Chairman MAGNUSON. Well, does the Federal Government actually do the immunization?

Dr. MCGINNIS. Grants to other organizations provide the immunizations. The Government itself, except in our direct service delivery programs, does not do the immunizations.

Chairman MAGNUSON. Give us an example of how it works.

Dr. MCGINNIS. An example of the direct service delivery program would be——

Chairman MAGNUSON. Where does the mother bring the child?

Dr. MCGINNIS. For the most part, the projects would be undertaking public information programs to raise the awareness of mothers, to first of all take her child to the private physician, her own physician. That's the system that we would like to see operative to the greatest extent.

Chairman MAGNUSON. But a lot of them don't have their own physicians. If they have them, they can't find them.

Dr. MCGINNIS. That's true. That is a problem in certain high-risk situations and in those cases we try to insure that public health service facilities operated by the city, the county, or in some cases the State are available for immunizing of the children and that mothers know precisely where they should go to receive immunization for the children.

Chairman MAGNUSON. But that only takes place in a dense urban center. What are you doing with the people outside the urban centers? Where do they go?

Dr. MCGINNIS. We have tried to insure that there are facilities available in every location, and one of the emphases has been on the schools. For example, we have tried to insure that moneys have been made available so a survey can be undertaken of every school system to identify the kids within those schools that haven't been immunized, and to provide for immunization of those kids regardless of whether it's an urban or rural location.

Dr. RICHMOND. Mr. Chairman, we are also concentrating on our rural and urban health centers, our community health centers, our Indian health service programs which have concentrated very well on an immunization program, and certainly we have used the schools since virtually all the States have mandatory immunization requirements.

Chairman MAGNUSON. I was going to ask that. Now in the schools you would be helping the State in disseminating the information and things of that kind?

Dr. RICHMOND. That's correct.

Chairman MAGNUSON. And we presume every school district has some kind of a clinic or place to go?

Dr. MCGINNIS. That's correct.

Chairman MAGNUSON. But every county in the United States has a county health office and they have a clinic and you can go down there. I have been down there to get a shot. Mothers are lined up with kids and they've got to go downtown and take an elevator up, there are no places to park, and the clinics are located in bad places. That's a local problem I suppose.

Dr. MCGINNIS. Well, it is a local problem, but it's one in which we would like to give whatever assistance we can to ameliorate. There's no question that one of the biggest concerns we have is insuring that every child—every newborn child in this country is followed up for immunization and that immunizations are made readily available. In fact, we are in the process now of instituting a comprehensive followup system to identify every vulnerable child and pull them into a system which can provide them not only with immunizations but comprehensive health care services.

Chairman MAGNUSON. Well, that would be up to the doctor, wouldn't it?

Dr. MCGINNIS. Well, in some cases these vulnerable children don't have their own physicians and we are trying to use, through epidemiological markers of sorts, characteristics of the mother, which children are not likely to have doctors and therefore——

Chairman MAGNUSON. But anyway, it's a program that relies upon its operation at the local level?

Dr. MCGINNIS. Absolutely.

Chairman MAGNUSON. And all you try to do is to help educate and things of that kind?

Dr. MCGINNIS. Exactly.

Chairman MAGNUSON. Well, the early school health education, we can talk about that a little later.

Dr. RICHMOND. Yes, indeed.

Chairman MAGNUSON. All right. Go ahead.

Dr. RICHMOND. We propose to call special attention through research, education, and other prevention activities to health problems caused by smoking and inadequate nutrition.

SMOKING AND HEALTH EFFORTS

Chairman MAGNUSON. What do you do, tell women that smoking causes cancer—cigarettes, not cigars? Everybody knows that now. What more can you do about it?

Dr. RICHMOND. Well, we think some significant progress has been made, Mr. Chairman. For example, when the first Surgeon General's report was issued——

Chairman MAGNUSON. I remember it well.

Dr. RICHMOND. There were about 54 percent adult males who were smoking. That's now down to about 42 percent. So men in our society seem to have gotten the message and seem to be doing something about it. We need to learn more about why they receive the message so well and women haven't received the message so well because they are smoking in about the same percentage that they were back then.

Chairman MAGNUSON. I understand all that, but what do you do? You've got some money in there or requests for money for dealing with the smoking problem by your office. What do you do? Do you put an ad in the paper telling people to quit smoking? Everybody knows about it. Do you issue a press release, which you seem to issue down there about once a week at least?

Dr. RICHMOND. Well, we certainly think that the press releases and the new Surgeon General's report have been having some effect, Mr. Chairman, because certainly there's a great deal of national interest.

Chairman MAGNUSON. We have appropriated some money for the Surgeon General but the report by the Surgeon General, that's a separate fund, isn't it?

Dr. RICHMOND. Yes.

Chairman MAGNUSON. That's under research, isn't it?

Mr. MILLER. The Surgeon General's report is not funded out of the research budget, no.

Dr. RICHMOND. Mr. Chairman, is it the educational efforts that you're interested in hearing about?

Chairman MAGNUSON. Yes. That's your job. I'm trying to differentiate. The Surgeon General has his budget estimate, doesn't he?

Dr. RICHMOND. Yes.

Chairman MAGNUSON. And the research is separate, isn't it?

Dr. RICHMOND. Yes; that's right.

Chairman MAGNUSON. And you're talking about education?

Dr. RICHMOND. Right.

Chairman MAGNUSON. All right.

Mr. MILLER. Mr. Chairman, I want to make it clear we have a request for $13.5 million for Dr. Richmond's office for this effort. Part of that, however, will be spent in conjunction with CDC and we will be working with them to help us with the health information parts of it. So it really covers both Dr. Richmond's office and CDC.

Mr. PINNEY. You asked a question earlier about how you get the message across and I might elaborate briefly. There's no question that the American people generally know smoking is dangerous. The problem we've found is they don't know about the specific dangers to them as individuals with other problems. For example, pregnant mothers are not generally aware of the risk they run to the unborn child if they continue to smoke. It's that kind of specialized message that we feel has never gotten across, for one reason, because we were not as clear about the evidence as we are now. That report is three times larger, almost four times larger than the 1964 report and the main reason is not because we put more words in it but because we know so much more. I don't believe it can get larger unless we go to two volumes. That clearly illustrates the problems. We've got so we know so much more and we can put the message in more specific terms for people who have more specific risks than just a smoker.

Another example would be women who take estrogen oral contraceptives. We put a message out to warn them of the high risk of heart attack if they smoke and take the pill.

It's those kind of special messages that we feel we have done little to get across.

Chairman MAGNUSON. I know what you're trying to do, but how do you do it?

Mr. PINNEY. The second part of that answer is: One, since 1975 the Department has put out no public television announcements. We are now preparing a major effort to put out new public service public television announcements on smoking which will be targeted to these people. Until the new initiative started we developed very little new information material based on that new evidence. We will be developing new brochures, new programs with professional groups such as general practitioners, with the obstetric and gynecological community to get the message out specifically in the waiting room, in the health clinic. We will be working through the health services administration in our own federally supported projects to get information brochures, to show public service spots, to do radio advertising aimed at teenagers. We will be hitting all the media at every opportunity we can.

Chairman MAGNUSON. In other words, you're using the media.

Mr. PINNEY. Not just the media, no. Every available physical and media means to get information across—doctors' offices, health clinics, schools—whatever is appropriate.

Chairman MAGNUSON. Fire departments?

Dr. RICHMOND. Yes, indeed.

Chairman MAGNUSON. I just want to know what you're doing with this money. I wrote the language that's on the cigarette packages.

Senator BAYH. Mr. Chairman, I wish you would read it.

Chairman MAGNUSON. We went over that for months. I don't know whether that gave you any help or not.

Dr. RICHMOND. We think it did.

Chairman MAGNUSON. But it seems to me that the cigarette, when you talk about tar and things of that kind, that it's not understandable to people. I don't think it is. People smoke a particular brand of cigarettes because there's less tar and more—I don't know what they call it—but I want to know what you do.

Mr. PINNEY. To get the information out. As Dr. Richmond said, Mr. Chairman, every time there's a major information effort smoking goes down. The per capita consumption of cigarettes goes down and we have seen already in 1978 that the per capita consumption is at its lowest point in over 10 years.

Chairman Magnuson. At least we've got the cigarette people in competition for what they claim is a safer cigarette and that's the purpose of their ads I guess. There's a full page every time you pick up a paper.

Senator BAYH. Mr. Chairman, are you going to leave that subject? Would it be appropriate for me to ask a followup question?

Chairman Magnuson. Go ahead.

Senator BAYH. I salute the Secretary and all of you for what I think is a courageous effort to do what I feel is one thing we can do that will help longevity and the health of our population more than anything else. I'm concerned whether the funding level is enough to do the job that has to be done. I'm concerned about our ability to target it. It's all well and good to talk about an informational campaign and I've got to believe education is the best way to go about this. But when we learn that 90 percent of the people that

learn how to smoke or smoke do so before they are 25 it seems to me that the educational program needs to be tareted.

In my judgment, rather than see these funds spread across the countryside in a thin layer, I'd rather see us put a big bale of it in the sixth grade. I think we have evidence to suggest that much of this thought process starts prior to the teen years and if we're talking about public service ads, what are we doing to make sure that some of those public service ads go around the Wheaties programs so the kids will get on their parents. Secretary Califano can tell you what kids can do to get you to stop smoking.

Chairman Magnuson. Kids don't smoke cigars.

Senator BAYH. That's right. Forgive me for needling you, Mr. Chairman. I know what a good sense of humor you have. If I didn't love you, I wouldn't do that.

Chairman Magnuson. I've never smoked a package of cigarettes in my lifetime, but go ahead.

Dr. RICHMOND. Senator Bayh, your comment about teasing those you love, Dr. Freud made that comment; that you tease only those you love.

Senator BAYH. He knows how I feel about him.

Chairman Magnuson. All right. Let's go on here.

Senator BAYH. Mr. Chairman, we didn't get an answer yet.

Dr. RICHMOND. Senator Bayh, as a pediatrician, I have been very interested in the very issues that you're talking about. We need to reach younger people so that they can understand the message and act on it. However we don't understand what makes certain youngsters in their adolescence vulnerable and why some resist. I'm sure there were many of your peers when you were going through adolescence who smoked. We need to know more about why adolescents begin to smoke. We have allocated some of the funding for the National Institute of Child Health and Human Development to this problem. We have suggested that they earmark $4 million of their research funding which was recommended last year for research in this area so that we can get a better understanding of what kind of messages tend to work more effectively.

We also recognize that the same efforts don't work at all ages. I was on the MacNeil-Lehrer show a few weeks ago the day the Surgeon General's report was made public. They interviewed on that show three teenagers and it was very clear they knew there were health hazards associated with smoking but they didn't accept that as having any particular relevance for them as individuals. So we need to know more about how to get the message across to the older adolescent, which is what these youngsters were. The younger adolescent or the preadolescent seems to yield to certain other kinds of messages that are more educational and indeed some of those youngsters put pressure on their parents to stop smoking when they learn more about it. So we know it's not going to be a homogeneous program. What Mr. Pinney and his staff are working on is really a cluster of programs designed for various age groups which will work, but we do need to have better scientific data on which to base our efforts.

Senator BAYH. I don't want to take any more time than that, but could we get a breakdown in the record of how this targeting is being planned. I think the business of zeroing in on mothers that

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are pregnant, even if you don't care for yourself, you're certainly going to be worried about the child. The fact that the one group we seem to have the biggest problem with are teenager girls, what are we doing there; black males, what have we done to try to find out why that continues to be a problem; as well as zeroing in on the younger population. If you could let us have some specifics, Dr. Richmond, I would appreciate that.

Dr. RICHMOND. Yes, certainly.

[The information follows:]

SMOKING AND HEALTH PRIORITIES

We have identified a number of target populations for our smoking and health programs. The most important are teenagers; it is essential to try to reduce the incidence of smoking among young people, for this determines smoking habits for many years to come. The second target group is comprised of current smokers who exhibit evidence of increased health risks associated with cigarette smoking. This group is comprised of pregnant women, women who take oral con-traceptives containing estrogen, people in industries where smoking adds to already existent industrial hazards, minorities, and persons already suffering from certain diseases or who are at extra risk of these diseases, as for example, persons with high blood pressure or high levels of cholesterol.

We have attempted below to show how the smoking and health funds are being spent relative to target groups.

OFFICE ON SMOKING AND HEALTH (OSH)

In fiscal year 1979 the OSH will spend approximately $850,000 of its $2.5 million on target groups. Activities include a national public information program aimed at target groups, a series of planning conferences on smoking and children for the purpose of identifying new approaches to smoking prevention, a major planning conference on the problems of smoking and racial and ethnic minorities, and the initiation of a series of other activities aimed at reducing smoking among young people.

The remainder of the OSH budget will be spent on scientific and support activities which are difficult to categorize in respect to target groups. An example of such an activity is preparation of the 1980 Report on Health Consequences of Smoking, a Report which cuts across all population groups.

In fiscal year 1980 approximately $11 million of the requested $13.5 million would be targeted at target groups. Ten million dollars of this would be allocated for grants to States and political subdivisions of States for demonstration programs to launch community and school-based prevention/education porograms to lessen smoking and alcohol consumption among children and adolescents.

In regard to other programs of the Department, it is possible to identify a number of educational and research activities for fiscal year 1980, which are targeted to specific groups. Among these activities are:

HEALTH EDUCATION—CENTER FOR DISEASE CONTROL

The Center for Disease Control will make grants to States to fund lifestyle or risk reduction projects with emphasis on smoking prevention among those at highest risk. For this activity, $3.6 million is being requested.

OFFICE OF EDUCATION—SCHOOL HEALTH

To initiate a new program to improve the health of elementary and secondary children, $2 million is being requested. Emphasis will be placed on activities to discourage smoking among young children.

NATIONAL INSTITUTES OF CHILD HEALTH AND HUMAN DEVELOPMENT

For research targeted toward children and smoking, $4 million is being requested.

NATIONAL INSTITUTE ON DRUG ABUSE

Approximately $300,000 of their $2.2 million request will be targeted at women, minorities, industrial workers, children, and adolescents.

OCCUPATIONAL HEALTH—CDC/NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH

The sum of $800,000 is requested to study the synergistic and additive effects of tobacco smoking and work-related exposures and to develop standards for restricting smoking in occupational settings where this interaction is harmful to workers.

FLUORIDATION

Chairman MAGNUSON. All right. Let's go ahead then.

Dr. RICHMOND. We, of course, are interested in increasing the awareness of children and adults to risks through school programs, through programs in the workplace, and through our community health centers. We are also interested in expanding screening and service programs targeted at identifiable diseases, such as hypertension, and vulnerable population groups; to encourage communities to fluoridate their water supply; to make an increased effort to prevent hospital-related infections; and to reduce the incidence of teenage pregnancy, and to provide health and support services for the pregnant teenager who chooses to have her baby.

Chairman MAGNUSON. Last year, the committee found that for every dollar we put into the fluoridation program, $36 was saved in the dental programs.

Dr. RICHMOND. Yes. The cost-benefit ratio here is very high.

Chairman MAGNUSON. What did you do last year to increase that? Give more information?

Dr. RICHMOND. Last year we didn't have an opportunity to go beyond a good deal of educational effort. In 1979 we have $1.5 million and this would establish 45 fluoridated water supply systems which would serve 400,000 people; also 60 rural schools—in the rural areas it's through the schools that we sometimes can make more advances—20,000 students will be reached.

Chairman MAGNUSON. You asked for $1.4 million more for the program in disease control.

Dr. RICHMOND. Yes, sir. That's where the program is based to do these things.

Chairman MAGNUSON. That's primary education, isn't it?

Dr. RICHMOND. No. That is also the fluoridation of the water supplies.

Chairman MAGNUSON. I mean it's educating the people as to the benefits.

Dr. RICHMOND. Yes.

Chairman MAGNUSON. That's basically what you do. You have sources of information and keep up with things and you try to spread it around the country. That's what it's all about.

Dr. RICHMOND. Yes. Our proposal for the 1980 budget is $6.2 million, so we think we will make a great deal of progress.

HEALTH SERVICES REFORM

Moving to the matter of health services reform, our health systems reform initiative is designed to improve the services to minorities and other unserved and underserved segments of our populations through an expansion of the National Health Service Corps, and an increase in the community health center program. Specifically, through the National Health Service Corps we propose to

place 1,100 more health professionals in underserved areas in 1980—a 63-percent increase over the current level. Further, the increased funding of the Community Health Center program will enable a total of 965 community health projects to serve an additional 710,000 needy patients a year. Of these centers, 34 are new rural health centers and 11 are new inner city health projects.

NEW RURAL AND URBAN HEALTH CENTERS

Chairman MAGNUSON. Give us a breakdown on where you plan to have them based, urban versus rural, will you?

Dr. RICHMOND. Yes, we will.

[The information follows:]

The selection of new rural and urban health center locations is determined through the competitive review process that would take place during the budget year. Funding of new centers would occur during the fourth quarter of the fiscal year. When the locations of these 45 new centers is known, a list of them will be provided to the committee.

HMO'S AND COST CONTAINMENT

Chairman MAGNUSON. I know we need both.

Dr. RICHMOND. Another reform of the health care service and delivery system includes efforts to assure a better geograhic and specialty distribution among health professions through funding:

First, to support the National Health Service Corps scholarship program where students pay back their scholarship through service in underserved areas; and

Second, funding to expand health professional education and training in the areas of primary care.

A third health services reform effort is the increased funding for health maintenance organizations:

First, to increase the number of projects, and

Second, to expand coverage of existing HMO grantees.

The budget request of $73.6 million for this program is nearly double that of the 1979 budget. We hope that our efforts to support HMO's will result in a total of 204 qualified HMO's by 1983, serving an estimated 6.1 million persons.

Chairman MAGNUSON. You must believe that the HMO is a good investment.

Dr. RICHMOND. Yes, indeed we do, Senator. We think in the service delivery system there are clear incentives in the HMO approach to prevention, for example, and for the reduction in hospital care than in any other form of practice. The incentives we think are very much built into that.

Chairman MAGNUSON. How do they fit into hospital cost containment?

Dr. RICHMOND. We think they fit in in a very basic way in that the rates of hospitalization among the beneficiaries in health maintenance organizations is about 30 to 40 percent less than the general population.

Chairman MAGNUSON. That's what I was going to say. That's what I've run into at home, that they were down a great deal.

Dr. RICHMOND. Yes. One of the best ways of conserving funding for hospital care is to keep people out of hospitals who don't need to be there.

Chairman MAGNUSON. And you're asking about double?
Dr. RICHMOND. That's correct.

MENTAL HEALTH AND ALCOHOLISM

Now our third priority area of mental health and alcoholism, we are trying to respond because we think the recommendations in the Report of the President's Commission on Mental Health were good recommendations. The report emphasized the need for improved services for the seriously mental ill and improved services for minorities, children, adolescents, and the elderly. It also focused attention on the need to enhance our research program in drug abuse, alcohol, and mental health research. The 1980 budget requests funding:

First, to provide more flexible funding for community-based mental health services and target those services on the neediest populations.

Second, to strengthen State mental health programs to improve services, especially for those with chronic mental illness and for severely disturbed children and youth, and

Third, to target new alcoholism service programs on high-risk populations, especially women and youth.

OVERLAP WITH EDUCATION BUDGET

Chairman MAGNUSON. Now in the education budget there's a great deal of money appropriated for disadvantaged children for rehabilitation and all that. How does this overlap?

Mr. MILLER. Well, the money that's appropriated for disadvantaged children, Mr. Chairman, is to cover the cost of their education. It's to bring them up to the level of those communities that are able to pay for a higher per capita cost. It isn't targeted toward any purpose such as alcoholism. It is true there's also a program for handicapped children, but that isn't targeted at any program in alcoholism.

Chairman MAGNUSON. I'm not talking about handicapped.

Mr. MILLER. None of that money overlaps this money. There's a very small amount of money in the categorical education for alcoholism. It's something like $5 million, but I'm sure there's no overlap.

Chairman MAGNUSON. Now the trouble with all these things is we're getting so we've got five or six different agencies handling it and we ought to put them together or at least try and put them together.

Dr. RICHMOND. I would think, Mr. Chairman, that most of the programs we are talking about will be referral resources for the schools. That is, where the schools find children who are in psychological difficulty they would be referring them to these resources. One can't very well put these kind of clinical programs in the schools.

Chairman MAGNUSON. Go ahead.

Dr. RICHMOND. Well, in reviewing the priorities I have just noted, I think it is important to point out that the requested funding in these areas includes dollars for research. For example, in the alcoholism and mental health initiatives, there is a request for a $30

million increase to improve prevention, diagnosis and treatment of mental disorders and alcoholism. And, in the prevention initiative, we are requesting that $28 million be spent for research relating to smoking and health. I personally am firmly committed to the need for continued health research dollars, since we still know too little about the causes, control, and cure of many significant diseases which place a significant burden on families and on our society.

[The statement follows:]

STATEMENT OF DR. JULIUS B. RICHMOND

Mister Chairman and Members of the Committee:

I am pleased to be with you today to discuss the Public Health Service appropriations for fiscal year 1980.

Before discussing the appropriations request for the Office of the Assistant Secretary for Health, I would like to summarize briefly for you the progress we have made in the past few decades in improving the health of our citizens, and then to outline our present priorities to improve the health of our citizens in the future.

Nation's Health

Today, the health of this nation's citizens has never been better. Life expectancy has increased to 73.2 years, an increase of 2.7 years over the past decade. This contrasts with an increase of one year in the previous decade. Since 1950, the infant mortality rate has been reduced by more than one-half and now stands at 14 deaths per 1,000 live births. Over the past twenty-five years the age adjusted death rate has decreased 25 percent. And, while heart disease continues to be the leading cause of death, between 1960 and 1976 there has been a 9 percent decrease in the death rate from heart disease.

The health of America's children is better now than ever before. Most of the common infectious diseases of children have all but disappeared. The eradication of small pox throughout the world has been a remarkable achievement. We have today a therapeutic armamentarium that would have been regarded as science fiction during my medical school days.

Yet, despite these noteworthy accomplishments there is still much that can and should be done:

--Significant differences still exist between blacks and whites in infant mortality and life expectancy rates.

- o In 1976 the black infant mortality rate was still almost twice as high as the white infant mortality rate.
- o Death rates continue to be higher for black people than for white people.

--As recently as 1976 a substantial number of children were not protected from preventable childhood diseases. To deal with this problem, the Secretary launched an immunization initiative in early 1977. The results thus far indicate that it is possible to correct this problem.

--42 percent of men and 32 percent of women still smoke, despite overwhelming evidence of the health risks associated with smoking.

--Heart disease and cancer continue to be the two leading causes of death, accounting for nearly 60 percent of all deaths.

--Mental disorders affect an estimated 15 percent of the U.S. population in any given year--almost 32 million people in 1975.

--An estimated 10 million people are reported as having a significant alcohol related problem. The overall increase in the drinking among youth is of particular concern. In 1974 more than a quarter of 12-13 year old male students and two-thirds of all 18-20 year old male high school students had at least one drink once a week, two drinks three times a month, or five drinks once a month.

* * * * *

The federal priorities I would like to outline for you now represent an attempt to respond to these problems. The majority of our requested increases in the 1980 budget are related to these priorities.

Specifically these priorities focus on:

(1) the prevention of disease and the promotion of health,

(2) the extension of health services to the unserved and underserved through reforms of the health care system, and

(3) the improvement of mental health and alcoholism programs.

Prevention

Our efforts in the area of the prevention of disease and the promotion of health call for funding:

- to continue efforts ensuring that at least 90 percent of all children are immunized against the major childhood diseases; we anticipate now that we can eliminate measles in the U.S. by 1982;
- to call special attention through research, education, and other prevention activities to health problems caused by smoking and inadequate nutrition;
- to increase information and awareness among children, as well as adults, of risks to good health--through programs conducted in schools and pre-school locations, the worksite, the community and health facilities;
- to expand screening and service programs targeted at identifiable diseases--such as hypertension--and vulnerable population groups;
- to encourage communities to fluoridate their water supply;
- to make an increased effort to prevent hospital-related infections;
- to reduce the incidence of teenage pregnancy, and to provide health and support services for the pregnant teenager who chooses to have her baby.

Health Services Reform

Our health systems reform initiative is designed to improve the services to minorities and other unserved and underserved segments of our populations through an expansion of the National Health Service Corps, and an increase in the Community Health Center Program. Specifically, through the National Health Service Corps we propose to place 1100 more health professionals in underserved areas in 1980--a 63 percent increase over the current level. Further, the increased funding of the Community Health Center program will enable a total of 965 community health projects to serve an additional 710,000 needy patients a year. Of these centers, 34 are new rural health centers and 11 are new inner city health projects.

Another reform of the health care service and delivery system includes efforts to assure a better geographic and specialty distribution among health professions through funding:

- to support the National Health Service Corps Scholarship program where students pay back their scholarship through service in underserved areas; and
- funding to expand health professional education and training in the areas of primary care.

A third health services reform effort is the increased funding for Health Maintenance Organizations:

- o to increase the number of projects, and

- o to expand coverage of existing HMO grantees.

The budget request of $73.6 million for this program is nearly double that of the 1979 budget. We hope that our efforts to support HMO's will result in a total of 204 qualified HMO's by 1983, serving an estimated 6.1 million persons.

Mental Health and Alcoholism

A third priority in the Public Health Service 1980 budget is to respond to the recommendations of the President's Commission on Mental Health. This report emphasized the need for improved services for the seriously mental ill and improved services for minorities, children, adolescents and the elderly. It also focused attention on the need to enhance our research programs in drug abuse, alcohol and mental health research. The 1980 budget requests funding:

- o to provide more flexible funding for community-based mental health services and target those services on the neediest populations.

- o to strengthen State mental health programs to improve services, especially for those with chronic mental illness and for severely disturbed children and youth, and

- o to target new alcoholism service programs on high-risk populations, especially women and youth.

The mental health initiatives, however, will first require the passage of new legislation which the Administration is supporting.

Conclusion

In reviewing the priorities I have just noted I think it is important to point out that the requested funding in these areas includes dollars for research. For example, in the alcoholism and mental health initiatives, there is a request for a 30 million dollar increase to improve prevention, diagnosis and treatment of mental disorders and alcoholism. And, in the prevention initiative, we are requesting that 28 million dollars be spent for research relating to smoking and health. I personally, am firmly committed to the need for continued health research dollars, since we still know too little about the causes, control and cure of many significant diseases which place a significant burden on families and on our Society./

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The well-known philosopher/historian, Will Durant, in his book, What Is Civilization, observed that "The health of a Nation is more important than the wealth of nations." I would add that by assuring and securing the health of this nation's citizens we can obtain our greatest national dividend.

DR. JULIUS B. RICHMOND

Assistant Secretary for Health

Dr. Julius B. Richmond was nominated June 9, 1977, by President Carter to be Assistant Secretary for Health, U.S. Department of Health, Education, and Welfare, and Surgeon General, U.S. Public Health Service. His nomination was confirmed by the Senate on June 28, 1977, and he was sworn into office July 13, 1977, by Chief Judge David L. Bazelon, U.S. Court of Appeals for the District of Columbia Circuit. He is the first Assistant Secretary for Health to also hold the position of Surgeon General of the Public Health Service.

Before coming to HEW, Dr. Richmond was Professor of Child Psychiatry and Human Development at Harvard Medical School and Chairman of the Department of Preventive and Social Medicine. At the same time he served as Psychiatrist-in-Chief at Children's Hospital Medical Center, and Director of the Judge Baker Guidance Center in Boston, a highly respected non-profit community-based mental health unit affiliated with the Boston Juvenile Courts.

As Assistant Secretary for Health, Dr. Richmond directs the activities of the Public Health Service, which includes the Alcohol, Drug Abuse, and Mental Health Administration, the Center for Disease Control, the Food and Drug Administration, the Health Resources Administration, the Health Services Administration, and the National Institutes of Health.

Dr. Richmond provides leadership and policy guidance for other HEW health programs including the new Health Care Financing Administration, which administers Medicare and Medicaid. He also maintains relationships with other governmental and private agencies concerned with health. He advises and assists the Secretary on health policy and on all health-related activities of the Department.

As the Surgeon General, Dr. Richmond will advise the public on health matters such as smoking and health, diet and nutrition, environmental health hazards, and the importance of immunization and disease prevention. He will also oversee the activities of the 6,000 member PHS Commissioned Corps.

Born September 16, 1916, in Chicago, Dr. Richmond received his B.S. degree in 1937 from the University of Illinois. Two years later he received an M.S. degree in physiology and an M.D. degree from the same institution. He served his internship at Cook County Hospital in Chicago and was a pediatric resident there and at Chicago's Municipal Contagious Disease Hospital in 1941 and 1942.

During World War II, Dr. Richmond served as a flight surgeon in the Air Force. In 1946, he joined the faculty at the University of Illinois College of Medicine as an Assistant Professor of Pediatrics, was promoted to Associate Professor in 1948 and to Professor in 1950.

From 1953 to 1971 Dr. Richmond served as Professor and Chairman in the Department of Pediatrics at the State University of New York at Syracuse. From 1965 to 1971 he was also Dean of the Medical Faculty. At Syracuse, he engaged in research in early childhood development, preventive medicine and family child health.

In 1971, Dr. Richmond was named Professor of Child Psychiatry and Human Development at the Harvard Medical School. In addition, he has served as the Vice Chairman of the Council of the Institute of Medicine of the National Academy of Sciences, Washington, and is a member of the Board of Directors of the Foundation for Child Development in New York City.

Dr. Richmond was appointed the first director of the National Head Start Program in 1965. The following year he became the first director of the Office of Health Affairs, Office of Economic Opportunity (which developed the Neighborhood Health Centers program). He has been President of the Society for Research in Child Development from 1967 to 1969, the American Psychosomatic Society from 1962 to 1963, and the American Orthopsychiatric Association from 1973 to 1974. Also, Dr. Richmond has served as Vice President of the Child Welfare League of America, and of the Society for Pediatric Research. He is a Fellow of the American Academy of Arts and Sciences.

Dr. Richmond is a member of the President's Commission on Mental Health and of the Massachusetts Department of Public Health Advisory Committee on Children.

Among his many awards and honors, Dr. Richmond was recipient of the C. Anderson Aldrich Award for Research in Child Development, the Parents Magazine Award "For Outstanding Service to Children," the Office of Equal Opportunity Distinguished Service Award, The John F. Kennedy Memorial Lectureship, Georgetown University Medical Center, and the Journal of Pediatrics Educational Foundation Lectureship, Emory University School of Medicine, Atlanta, Georgia.

July 1977

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
Statement by the Assistant Secretary for Health
on
The Office of the Assistant Secretary for Health,
Scientific Activities Overseas and
Retirement Pay and Medical Benefits for
Commissioned Officers

Mr. Chairman and Members of the Committee:

I am pleased to be here today to request funds for three Appropriations--the Assistant Secretary for Health, Scientific Activities Overseas, and Retirement Pay and Medical Benefits for Commissioned Officers.

Assistant Secretary for Health

The 1980 budget request for my immediate office includes a number of important new health initiatives which represent high priority efforts for the Public Health Service. We are requesting $260.6 million of which $238.8 million is for specific health programs and $21.8 million for overall PHS management functions.

National Center for Health Statistics

The National Center for Health Statistics is the principal organizational focus in the United States for the collection and analysis of health statistics. Periodic surveys and inventories are conducted on a number of topics including marriage and divorce rates, nutritional status, natality, mortality, and morbidity. Data gathering activities also include topics such as facilities, manpower, and utilization of services. The National Center for Health Statistics supports the Cooperative Health Statistics System which is designed to produce comparable and uniform health information at the National, State and local levels on vital statistics, manpower and facilities characteristics.

The 1980 Health Statistics budget of $48.6 million provides for an increase of $9.3 million over 1979 to initiate and expand efforts in the areas of epidemiology and the effects of the environment on health, as required in the 1978 legislation. Another major initiative to be supported is the National Medical Care Utilization and Expenditure Survey. This program will be carried out in collaboration with the Health Care Financing Administration. The information to be collected on health characteristics, health services utilization, and health care expenditures is needed to monitor current health care financing, and to plan strategies for national health insurance. These data would be used to monitor changes in the use of health services and in expenditure patterns. The requested increase will also support the Cooperative Health Statistics System for implementation of the Vital Statistics and Health Manpower components in all fifty States, the District of Columbia, and Puerto Rico, and will finance the establishment of State statistical centers.

National Center for Health Services Research

The National Center for Health Services Research undertakes and supports research, demonstrations, and evaluations that address the problems associated with the delivery of health services in this country. The center performs and supports research directly related to immediate policy concerns as well as stimulating and supporting more long-range research issues. Major activities currently supported are analyses of the National Medical Care Expenditure Survey, cost containment, research for health planning, hospital cost analysis, and manpower analysis.

The budget request of $29.3 million will provide for the initiation of a research training program and for the continuation of the health services research program and dissemination activities.

Health Maintenance Organizations

The Health Maintenance Organizations activity works to give consumers an alternative to the traditional practice of fee-for-service medicine, for improved access to the health system, complete medical care coverage including ambulatory care and increased competition in the health marketplace. HMOs have demonstrated their effectiveness in restraining health care costs primarily through significant reductions in hospital utilization rates.

The budget request of $73.6 million, an increase of $34 million over the 1979 level, will fund 66 grantees in the initial development phase during which time they either complete all activities necessary to place the HMO in operation or significantly expand services provided in order to accelerate enrollment.

Special Health Programs

A major Departmental initiative is to expand efforts in disease prevention and health promotion. A vigorous and expanded health information and health promotion program will be supported within this budget request. An increase of $3.6 million is requested to support public service announcements and other carefully planned uses of television and radio to heighten public awareness with respect to measures each individual can take to improve health and reduce health risks through changes in behavior. The National Health Information Clearinghouse will receive increased funding in this request. Another facet of the prevention effort is a comprehensive program to deter smoking and the use of alcoholic beverages among children. In 1980, a $10 million grant program will be initiated to fund community-based smoking and alcohol prevention and education programs targeted specifically at children.

International health activities will take on new importance in 1980. A basic part of the President's international health initiative is a commitment to more effective coordination of policy within the government and of both public and private activities. The request of $2.9 million will assist in developing a framework to assure that policies and priorities in international health are consistent throughout PHS.

Adolescent Health Services

One of the most alarming problems facing our Nation today is that of adolescent pregnancy. Approximately one million teenage girls--one out of every ten--become pregnant each year. The majority are unmarried, and their pregnancies are unwanted. Our major concern is the incidence of adolescent pregnancies throughout the Nation, the complex medical and social problems resulting from such pregnancies, and the unavailability of appropriate medical and social services to adolescents to prevent or alleviate these problems. In fiscal year 1980 we are proposing to significantly expand the grant program for public and private nonprofit entitites to assist them in operating projects to provide the much-needed comprehensive community services. The 1980 request of $60 million will permit a far-reaching grant program to assist pregnant adolescents and adolescent parents to obtain needed medical, social, educational, and other services that will help them to become productive independent contributors to family and community life. The short-term costs of meeting these needs will be far out-weighed by the long-term savings on welfare costs, and by substantial improvements in the quality of life for a major segment of our society.

Health Care Technology

Our concern about the proper utilization of medical technologies will be addressed through the $5 million requested for the new National Center for Health Care Technology. Funds will be used to support projects to identify technologies which have been insufficiently reviewed and studied. In addition, efforts will be directed toward stimulating the adoption of practices, procedures, and devices whose usefulness has been demonstrated.

Since the preparation of this budget, the Office of the Assistant Secretary for Health has been reorganized. Information will be provided for the record to relate the budget before you to the new organizational alignment.

1979 Supplemental Budget Request

In addition to the 1980 budget proposals, we are requesting a 1979 supplemental appropriation of $23.5 million, which includes $16.5 million for the health maintenance organization program and $7 million for adolescent health services. Included in the request for HMOs are funds to implement a new management training and technical assistance program to professionally train managers and prospective managers of HMOs to improve the quality of management in operating HMOs. This program was authorized in the HMO Amendments of 1978. The balance of the supplemental request for HMOs would support expanded grants activity resulting in part from the comprehensive promotional plan initiated in fiscal year 1978. As these promotional efforts continue, demand for HMO grants will increase. The additional projects to be funded in 1979 will generate approximately 47 HMOs which, at maturity, will serve 1.4 million enrollees.

Our commitment to starting new HMOs and expanding existing HMOs reflects the desire to limit unnecessary expenditures and to ensure that significant numbers of people across the Nation have the opportunity to enroll in HMOs.

The funding request for adolescent health services will enable us to implement the recently authorized grant program to provide assistance to pregnant adolescents. The seriousness of this problem warrants our immediate attention. Funding priority will be given to areas where there is a high incidence of adolescent pregnancy and to areas where there are a large number of low-income families and few adolescent services are available. Special consideration will also be given to rural projects.

Scientific Activities Overseas

The 1980 budget request of $6.5 million together with funds carried over from 1979 will be used to fund health research and related activities in participating foreign countries at the 1979 obligation level. These activities are related to our domestic health programs and contribute to the achievement of the overall goals of the Public Health Service. Activities are supported entirely with United States owned excess foreign currencies.

Retirement Pay and Medical Benefits for Commissioned Officers

The 1980 request of $76.9 million will provide payments to retired PHS Commissioned Officers and survivors of deceased officers. Funds are also used for medical care for dependents of eligible personnel of the Coast Guard, the National Oceanic and Atmospheric Administration, and the Public Health Service; and to retired personnel of these services. The increase of $11.8 million over 1979 includes $6.9 million for dependents' medical care, $4.7 million for retirement payments, and $.2 million for survivors' benefits.

Mr. Chairman, I will be pleased to answer any questions you may have on these requests.

RESEARCH FUNDING

Chairman MAGNUSON. Now you get down to the question I just asked. Who's getting the money for research; the Surgeon General or you people, or both?

Dr. RICHMOND. The research funding is in the National Institutes of Health and the National Institute of Child Health and Human Development and the National Heart, Blood and Lung Institute. Certainly the Alcohol, Drug Abuse, and Mental Health Administration also has significant funding for research in these areas.

Chairman MAGNUSON. Well, of course, these agencies coordinate with the Surgeon General's Office and the Assistant Secretary for Health. Do you divide these funds for research?

Dr. RICHMOND. No, sir. These research funds are in the budgets of the National Institutes of Health and in the ADAMHA. They are not in the Office of the Assistant Secretary or the Surgeon General, but we are trying to stimulate those agencies.

Chairman MAGNUSON. $28 million goes for the Surgeon General and all these things that you do; is that right?

Dr. RICHMOND. No, sir. That money is requested in the appropriations request for the National Institutes of Health.

Mr. MILLER. It's all under his direction, Mr. Chairman, but you appropriate the money directly to the agencies.

Chairman MAGNUSON. That's sent out to the agencies to aid in their programs of research on specific things?

Mr. MILLER. That's right.

ADOLESCENT HEALTH PROGRAM

Chairman MAGNUSON. All right. I think we've covered most everything. In the 1979 supplemental request for a new adolescent health service program, why is this new program needed and why is it located in your office?

Dr. RICHMOND. Senator, this is a program which Dr. Nix is directing. Because of the significant problems that we have identified in the area of adolescent health and pregnancy, we determined that a new effort was needed. This effort goes beyond anything that we have developed thus far because if we're going to deal with the problems of adolescent pregnancy we need to put some programs in place that go beyond purely medical services offered by our existing agencies.

We, therefore, think that it is important for that program to be in the Office of the Assistant Secretary because that program needs to be linked with the educational system, with the welfare system, with human and development services of the Department; and in order to do that well, to draw on these various other agencies, we think that comes better from the Office of the Assistant Secretary than it would be if that were an operating program in one of the health agencies.

PHS HOSPITALS

Chairman MAGNUSON. Now there's a slight cutback of funding for PHS hospitals. Why is that?

Mr. MILLER. I think primarily, Mr. Chairman, that has to do with one-time costs. Some of the funds in fiscal year 1979 are for purchase of equipment for repairs and improvements and we believe we can maintain the current level with the appropriation request that's before you without any diminution in services in the hospitals.

Chairman MAGNUSON. Well, what you're doing is making them absorb a $12 million decrease. That straps them pretty good.

Mr. MILLER. My understanding of the way we calculated the pay raise, Mr. Chairman, is that we can maintain the services and still absorb the pay raise.

Chairman MAGNUSON. But the services are increasing. The services are going to be increased. The services that they give to the communities is going to be increased?

Mr. MILLER. Of course, we don't know yet exactly what community services we'll be recommending following the task force report and the work we're doing now to talk to the health services agencies. So we do not know whether we would recommend an increase in services yet or not. We are not doing it for fiscal year 1980 but it's possible that as a result of our followup on that report we will request it next year.

Chairman MAGNUSON. Well, now the Secretary looked at the one in Seattle and he was very impressed with it, and it came out No. 1 in the report, too. Later they're going to have an increase in services. The population is increasing out there. They are going to have an increase in services.

Mr. MILLER. Mr. Chairman, I need to check this for the record, but I think there's enough money in the budget for us to maintain any occupancy rates that are required by the service needs in the area.

Chairman MAGNUSON. We're not talking about occupancy rates here. We're talking about outpatients.

Mr. MILLER. I guess what I'm saying is we're not going to turn away anybody for lack of funds. We will be able to meet our obligations with the money available. It's possible we won't be able to go as far as the task force report recommended on such matters as community health and research, but we will take care of our beneficiary population.

Chairman MAGNUSON. Well, I would suggest that you put some more money in the Public Health Service hospitals.

Now the House turned down the child health facility and I'm not going to ask you about it. We'll have to take care of that. I want you to be reminded of this, too—public law mandates certain operating levels for PHS hospitals and clinics. If it's obvious that level is going to go up 15 or 20 percent, it's mandated that you put enough money in the budget by law.

Mr. MILLER. I'm virtually certain, Mr. Chairman, that we are meeting the law with respect to what it requires in this instance. That law relates to our beneficiary population.

TRAINING STIPENDS

Chairman MAGNUSON. Now during our NIH hearings we found the training stipends have become a serious problem at NIH.

$10,000 is the amount provided for the training people to work in biomedical research and this is also a $5,000 cut from what these students received as medical fellows. What do you have to say about that?

Dr. RICHMOND. Well, Mr. Chairman, this is a very serious problem which Dr. Frederickson, along with us, is very concerned about. The stipends have indeed been low. I think we have been lulled into a false sense of security about them because it seems to be quite possible to fill the positions. It isn't proper to ask people in that stage of their career to have stipends quite this low. Also there seems to be an effect that's taking place in terms of the physicians who are not taking these postdoctoral fellowships—these training positions—because of the fact that they can earn so much more in other pursuits and they do have other pursuits open to them. We are reexamining our policy on this and we hope we can come up with some better solutions.

Chairman MAGNUSON. What do you have to say about categorization? Let's go back the other way. What can we do to help this out? Should we dictate a higher level in our report or suggest it?

Dr. RICHMOND. Well, that's one approach.

Chairman MAGNUSON. That would be the only approach we could take.

Dr. RICHMOND. The only other approach would be to reduce the numbers of fellowships and trainees, which we think would not be in the national interest.

Chairman MAGNUSON. Well, training across the board—in HEW—always seems to take a back seat and I don't know how we're going to—well, Larry reminds me—could you put in the record how much it would cost to finance them at $15,000 instead of $10,000? What the added cost would be?

Dr. RICHMOND. Well, it would probably be at least $50 million. However, if the increase in the stipends is lower the total cost could be significantly less.

CAPITATION RESCISSION

Chairman MAGNUSON. All right. Now why do you think we should accept your rescission request on capitation?

Dr. RICHMOND. Well, sir, the purpose of the initial capitation legislation was largely to increase our output of people in the various health professions. We, particularly with physicians at the present time, certainly feel that the institutions have responded, that we are turning out an adequate number of physicians, and that our projections for the future would be a favorable population-physician ratio. We think under these circumstances it doesn't make sense to continue to provide the funding for maintaining an increased output. That is, when that is no longer a need.

Chairman MAGNUSON. What about rural problems, maldistribution? That's the bottom line really. Some places don't have enough health professionals and some places do.

Dr. RICHMOND. But it's quite clear, sir, that just turning out more health professionals hasn't in and of itself corrected the maldistribution problem. We seem to be getting a much better

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effect in redistribution through the National Health Service Corps than we were getting by just turning out more.

Chairman MAGNUSON. Well, the redistribution comparatively doesn't deal with the present problem. It deals with the future problem. It's more of an adjustment.

Dr. RICHMOND. The National Health Service Corps has begun to deal with the problem and is a very effective way of getting to it.

Chairman MAGNUSON. Well, too many doctors in one area and you're not going to get them to move out. You're dealing with the future.

QUESTIONS SUBMITTED FOR RESPONSES

All right. Senator Schweiker has some questions he wants to ask for the record and you can answer those for the record. I hope that you can get these answers back in a week because we are moving pretty fast. Thank you very much.

Dr. RICHMOND. Thank you very much, Mr. Chairman.

[The following questions were not asked at the hearing, but were submitted to the Department for response subsequent to the hearing:]

Questions Submitted by Senator Schweiker

TARGETING HMO FUNDS

Question: Could you describe to us your plan for targeting HMO funds at particular areas of the country?

How were these areas chosen?

Over how long a period will this targeting program extend?

Answer: Over the last several months we have been formulating a targeted community development strategy to improve our efficiency and success in the use of federal dollars for HMO development. The HMO program will direct a portion of its funds toward 61 targeted SMSAs. The program will give priority to these targets, both in promotional activities and in the disbursement of grant funds for expansions and new programs. We will continue to fund HMOs in non-targeted communities on a second priority basis. We will also continue our efforts to bring HMOs to rural and medically underserved areas.

The target areas chosen include SMSAs with a population base of at least 250,000 where HMO growth has generally been slow. Some of the locations are SMSAs with high health care costs combined with large populations. Although these complex markets are among the most difficult for HMO development, they exhibit the greatest long-run potential for enrollment and subsequent savings of health care expenditures. Other targets were selected because their high growth rates and mobility indicate an immediate favorable climate for HMOs.

The targeted approach to HMO development will guide our resource allocations over the next ten years. We will concentrate on a manageable number of communities each year. We expect the competitive impact of these HMOs to result in both considerable savings to the health care system in that community and additional HMO growth.

HMO POSITION REALLOCATION

Question: Last year, HEW requested the authority to reallocate 37 positions, and indicated how they would be distributed among the various Branches of the HMO Office. Has that reallocation been completed and does it conform with the allocations described to the committee in the original request?

Answer: All 37 positions have been filled. The original request was to add 13 new positions to qualification to bring the total to 25, add 23 new positions to compliance to bring the total to 32, and add 1 new position to administration.

The Division of Compliance now has 32 full time permanent employees; the Division of Qualification has 21. Over the past year the backlog of applications in the Division of Qualification has been significantly reduced. The current workload in this Division does not require more than 21 employees. The remaining four (4) positions are being used to support the overall effort of these activities in areas such as regulations and policy development and loan monitoring.

UNDERSTANDING THE HMO CONCEPT

Question: I understand one of the major problems facing HMOs around the country is misunderstanding of the HMO concept by health planning officials, especially officials of local health systems agencies.

What efforts has HEW made, perhaps through the cooperative efforts of the planning and HMO Offices, to enhance the understanding by planning officials of the HMO concept?

Do you feel that more educational activities of this kind are in order?

Answer: The Department is anxious to enhance understanding of HMOs among health planners. On March 17, 1978 proposed regulations were published in the Federal Register outlining review criteria for Federal Financial Assistance Reviews by Health Systems Agencies (HSAs) and State Health Planning and Development Agencies (SHPDAs). The final regulations are presently under review in the Office of the Secretary and we expect their publication shortly. In the same March 17, 1978 Federal Register, regulations were published under the regulatory authority of the Bureau of Health Planning. Development of these sets of regulations resulted in a strengthened and closer working relationship between the Bureau of Health Planning and the Office of Health Maintenance Organizations.

The Office of Health Maintenance Organizations has been working to collect and analyze data on the HMO relationships with health planning agencies, especially Health System Agencies. The program compiled case studies of problem experiences, in cooperation with the Group Health Association of America, outlining specific experiences in approximately ten HMO application reviews by health planning agencies. In addition, the Bureau of Health Planning cooperated with the HMO program by funding a consulting company, Analysis Management Planning Institute (AMPI), to obtain an inventory of HMO decisions by health planning agencies and to analyze 12 case studies of both positive and negative reviews by these agencies. We expect that completion of this contract will provide the Department with more information on HMO and health planning relationships.

In spite of these cooperative efforts, developing HMOs remain plagued by problems. Certificate-of-Need applications

continue to have a difficult time "winding" their way through the health planning process. Without question more educational activities are needed and we are anxious to see:

-- Educational sessions conducted by the Bureau of Health Planning for the HMO program staff and vice versa;

-- Joint educational activities in cooperation with health planning agencies to educate both health systems agencies and state agencies' staff and board members.

Health Planners need to be educated so that they:

1) Avoid the use of unrelated criteria in HMO review.
2) Avoid duplicating the federal review of certain elements in grant and loan applications such as financial viability determinations.
3) Complete reviews of HMO financial assistance applications within 60 days.
4) Require no more than 90 days for SHPDA reviews for Certificate-of-Need.
5) Include an HMO section in all State Health Plans and Health Systems Plans.
6) Propose new review criteria by HSAs or SHPDAs consistent with Title XIII.

Finally, the Department is anxious to see enactment of the HMO section of its health planning amendments, which will be submitted to the Congress shortly. Enactment and implementation of this provision should aid in educating planning officials' on HMOs.

HMO OFFICE EMPHASIS

Question: There are those who argue that until the HMO Office and its new reorganization plan are more fully established, there should be a greater emphasis placed on grant and loan management and less on promotional activities.

How do you respond to this suggestion?

Do you feel it might be a better idea to increase the number of personnel in the Loan and Compliance branches with some of the slots now being used for promotional activities?

Answer: Our grant and loan program has not been neglected or sacrificed by the program's promotional activities. Over the past year both the grant/loan and compliance divisions have been strengthened considerably. Several managerial and administrative reforms have been implemented including prequalification guidelines and review process, preparation of a written loan policy manual, loan monitoring training, technical assessments of developing plans, quality assurance strategy, and a compliance monitoring program including the early warning system and data monitoring.

While the promotion activities of the program perhaps generate the most visibility, they in fact represent the smallest program commitment in terms of staff and resources. Of a total 111 full time permanent positions, the promotion division consists of 7 professionals and 3 support staff. This core staff works to promote increased public awareness of the HMO concept nationwide and responds to public inquiries (for example, the toll free "hotline" averages 25 phone calls per day and, depending on press coverage and public media response, can reach up to 100 per day). In addition, this division manages the marketing effort of the program which provides direct information and assistance to potential sponsors of HMOs, including stimulating the employer/corporate market in order to increase enrollment in existing operational plans. Also, the National Industry Council on HMO Development relies on staff support provided by the promotion division. Finally, this staff is responsible for development and production of educational and informational materials helpful to consumers, providers, labor and business. All of these activities help the operational and developing HMOs.

Perhaps HEW's most important role in the promotional area is that of providing leadership to the HMO movement nationwide. The personal involvement of the Secretary, Under Secretary, and Director of the program represent the major Departmental commitment. Our promotional activities serve the long term goals of national HMO development and we strongly oppose transferring slots from promotion to other areas of the program. If anything, we are anxious to strengthen further our market development capabilities so that we are better able to meet the needs of young operational HMOs.

IMPLEMENTING NEW AUTHORITIES

Question: Would you describe what steps you have taken to implement the management training and technical assistance authorities provided to HEW in the 1978 Amendments?

Answer: We will be fully prepared to implement the management training and technical assistance authorities as soon as funding becomes available. Since enactment of P.L. 95-559 last fall, much analysis has gone into the best way to implement both these authorities.

After review of programs in various Federal agencies to ascertain whether there might be acceptable models for management training, we determined that no comparable program exists which is geared toward delivering training to managers in a private industry. Therefore, we proceeded to consult extensively with representatives of the HMO industry, management trainers from selected universities, and consultants. Several approaches for implementing this authority were addressed in mid-February at the National HMO Policy Conference, where more than fifty representatives participated in a discussion. Since this dialogue, we have refined further the program direction for implementing the new authority.

We are recommending to the Secretary that the program focus, in its initial phases, on upgrading the managerial capabilities in operational HMOs and advanced preoperational projects. Three approaches are under consideration: classic internships, a series of management workshops and conferences, and development of a national HMO training resource center. Once final implementation decisions are reached within the Department, we will proceed to issue regulations and funding criteria.

With respect to the technical assistance authority, our intention is to provide needed technical assistance to developing and operating health maintenance organizations in the most effective possible way. This technical assistance could be provided in several ways such as:

- Grants or contracts to operating HMOs--experienced HMO staff would provide technical assistance in all areas of development and operations to organizations facing similar experiences;

- Contracts with trade or professional associations affiliated with the HMO movement and funding of HMO consortiums; and

- Contracts with consulting firms with expertise in various specialty areas of HMO development.

REGIONAL OFFICE ROLE IN HMO PROGRAM

Question: What efforts has HEW made to enlist the resources of the regional office in improving the administration of HMO grants and loans?

Answer: Grants -- The regional office role in administering grants is to both monitor grantee activity and review applications for continued funding. The central office developed, with significant input from staff of regional offices, extensive guidelines intended to maximize regional office participation in grantee monitoring and application review. A system for monitoring has been defined and includes regular regional office site visits, consultation with grantees, and review of written materials and reports submitted by grantees.

Loans -- The central office recently developed a loan monitoring protocol. We used this protocol to provide training to the regional office staffs to assist them in monitoring HMO and escrow agent compliance with the terms of HMO loan agreements. A primary regional office loan monitoring responsibility is to ensure that loan advances are made in accordance with the approved schedule, as well as to ensure that loan funds are not drawn by the HMO in excess of operating deficits.

In addition, the HMO program instituted a regional office work planning system with measureable milestones. We think

its implementation strengthens regional office capability to administer their grant and loan responsibilities. This system includes identification of tasks and time required to administer HMO grants and loans. The regional offices fully participate in development of the workplans and negotiations of region-specific goals. We are now in the process of verifying the first year's experience. This verification is almost totally dependent on regional office input. It should help us to improve and refine the system for next year.

HMO REGULATIONS

Question: What regulations for provisions of existing law have yet to be promulgated?

Answer: An outline of the status of all regulations for the Office of Health Maintenance Organizations is attached. The HMO program is well along with its plan to implement new authorities under P.L. 95-559, the HMO Amendments of 1978. When the new authorities became law, the program immediately began to draft new regulatory language so that the appropriate regulations would be changed as soon as possible to conform with the amendments. The loan section of the regulations was amended on February 22, 1979, to permit eligible HMOs to receive increased loan assistance as authorized by Public Law 95-559.

HEW will be making every effort to expedite the review and issuance of these regulations.

Question: Have the regulations for the fraud and abuse sections of the 1978 amendments been fully promulgated and implemented?

Answer: The financial disclosure requirements of Section 1318 of the Act are being incorporated into subpart A regulations. They will be published as interim regulations and are to become effective on the date of publication in the Federal Register. As a result, the long delays in rulemaking can be held to a minimum and the financial disclosure requirements can be implemented as soon as these regulations are published. These rules should begin the Departmental clearance process by the end of April.

Office of Health Maintenance Organizations
Status Report on Regulations

Subpart and Title	NPRM	Interim/Final	Due in OGC for Clearance 1/
A - Requirements for an HMO	9/11/78	6/8/77 (interim)	4/5/79
B - Federal Financial Assistance: General	3/17/78	6/8/77 (interim)	3/15/79
C - Grants for Feasibility Surveys		10/27/78 (final)	4/30/79
D - Grants and Loan Guarantees for Planning and Initial Development Costs		10/27/78 (final)	4/30/79
E - Loans and Loan Guarantees for Initial Operating Costs 2/		2/22/79 (interim)	4/30/79
F - Qualification of HMOs		6/8/77 (interim)	4/16/79
G - Restrictive State Laws and Practices		10/18/74 (final)	Not contemplated
H - Employees' Health Benefits Plans		4/25/78 (interim)	3/16/79
I - Continued Regulation of HMOs and Other Entities		7/25/78 (final)	4/23/79
J - Reconsiderations & Hearings 3/	9/17/76		3/1/79
- Management Training 4/			5/1/79

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1 Official clearance is required by PHS/ES, OS/ES, and must be approved by the Office of the Secretary before publication in the Federal Register. Because each set of regulations involve circumstances and issues at varying levels of resolution, OHMO is unable to establish publication dates.

2 Additional regulations under development to implement construction and acquisition of ambulatory health care facilities - Section 1305A of the Public Health Service Act, as amended; to be published as an NPRM.

3 NPRM being withdrawn, procedures incorporated in other sections of 42 CFR Part 110.

4 OHMO position paper has been developed to implement Section 1317(a) of the Public Health Service Act, as amended.

HMO COMPLIANCE MONITORING

Question: Under the existing compliance program, how many HMOs will each compliance officer be assigned to monitor for financial difficulty?

Answer: At the present time, the Division of Compliance has assigned up to 10 HMOs to each compliance officer to monitor for financial difficulty. Two financial specialists in the Division participate with the compliance officers in monitoring the HMOs, as well as the staff in the program's Loan Branch. The early warning system and the newly organized compliance process will be evaluated to determine the long term impact on efficiency of operation and future staffing needs.

Question: How will the implementation of the new computer system affect this workload?

Answer: Implementation of the new computer system will assist compliance officers in doing a more efficient and thorough job. The computer will perform tedious screening and analyses in a fraction of the time it currently takes compliance officers. In addition, compliance officers will be free to cover more aspects of a plan's compliance in greater depth than ever before because of the computer's assistance. An effort will be undertaken within the next six months to measure the impact the computer system will have on staff efficiency to more appropriately determine the staffing ratios for compliance monitoring.

Question: Do you feel the number of staff in the Compliance Office is adequate to detect possible waste or abuse of government money?

Answer: Detection of major waste or abuse of government money is achieved through systems to manage and screen operating information required by HEW from HMOs. We believe that our present staffing is adequate when combined with computer capability. Also, we have developed a close working relationship with the Office of the Inspector General (OIG) in HEW so that in-depth audits can be initiated whenever we identify the possibility of waste or abuse. In addition, we will be supporting a Public Health Service contract for auditing services when neither our staff nor the OIG staff is available to conduct necessary audits.

In implementing the reporting requirements of Section 1318, we will be obtaining information on affiliated organizations and parties of interest including details of the financial transactions between the affiliated organizations and parties

of interest and the HMOs. When the HMO can not adequately support the reasonableness of these financial transactions in the context of the "prudent buyer concept", appropriate compliance actions and loan actions will be initiated after evaluations by our staff, the staff of the Inspector General and expert financial consultants.

We are able to detect only gross situations of waste and abuse. The responsibility for examining detailed financial transactions of an HMO that may be identified as possibly wasting or abusing federal funds rests with the Office of the Inspector General. Therefore, we recognize the need to maintain close cooperative working relationships with the offices cited above.

QUALITY OF HMO CARE

Question: One of the concerns that has been expressed by those skeptical of the HMO movement is that HMOs might provide lower quality of care. HMO advocates have steadfastly maintained that this is not true.

What is the HMO Office doing to ensure that the level of care provided by federally qualified HMOs remains high?

Answer: HMOs provide built-in incentives to offer good quality, continuous care including preventive services. No evidence has been offered to show that qualified HMOs provide low quality care. Most HMOs have strict requirements for selection of physicians who participate in the HMO. In its qualification reviews, the HMO program looks carefully and critically at the HMO's health services delivery system including member/physician staffing ratios, facilities to be utilized and the availability and accessibility of health care services. In compliance monitoring, these parameters are again routinely examined, along with utilization rates and member complaints, which may indicate problems in quality. If serious problems are suspected, formal review and evaluation is triggered.

In addition to these activities, we require qualified HMOs to have an internal quality assurance program for assessing and improving the quality of care. Over the past year we have developed a refined quality assurance program for HMOs; its full implementation will assure that there are systematic and objective examinations of suspected problems in health care. Where problems exist, HMOs will institute specific improvements to correct them. Individuals outside the HMO will periodically conduct an external assessment to examine the effectiveness of the internal quality assurance program. You may recall that public hearings were held last summer and they generated much interest and participation by the industry and others outside the Department. The final draft of our quality assurance program is now being publicly reviewed.

HMO APPLICATION PAPERWORK

Question: What efforts has the HMO office undertaken to consolidate or decrease the amount of paperwork an HMO has to go through in order to obtain federal grant money?

Have there been any efforts to integrate the paperwork requirements of state HMO laws with those of the federal law, as the Senate Committee Report on the 1978 HMO Act Amendments suggested?

Answer: We do not think that current requirements are onerous. They reflect the statutory requirements in section 1306 and our four year experience with the grant program. We think our requirements identify the key elements necessary to ensure successful development by grantees. We do agree that most applicants submit far too much paperwork. We are working to correct this problem in two ways:

- First, a concerted effort is underway, with the help of our regional office staff, to convince applicants that they need not overwhelm us with paper. Our concern is that they provide us with accurate basic information. We are determined to require only information necessary for an informed judgement about whether grant funds should be awarded.
- Second, we've had an initiative to provide applicants with more precise guidance about what we require and how their application will be evaluated. The review standards we have developed and are now testing will accomplish this by spelling out more clearly the information upon which a funding decision will be based at each phase of development from feasibility to initial development.

We should note that historically the paperwork burden caused severe problems for qualification applicants. A major project this past year was the revision and simplification of the application form so that we require only essential and useful information. Management of operating HMOs who field tested that application now in use, indicated that we reduced the time required to complete a qualification application by as much as 50 percent.

HMO EXPANSION GRANT STAFF

Question: How many new staff will be assigned to the Development Division of the HMO Office in order to process applications for the new expansion grant monies made available as the result of the 1978 Admendments? Do you feel this Division can handle this additional workload without more staff?

Answer: The Fiscal Year 1980 budget request includes an additional nine positions primarily to enhance our capacity to manage the expanded number of grants and to help monitor loans. Expansion grants currently are being processed within 120 days or sooner which we believe is a prompt and responsive time period. We believe the proposed staff complement is sufficient to handle the expanding HMO workload for FY 80.

HMO FISCAL DATA

Question: How is the data on HMO fiscal soundness that is fed into the computer program collected?

Answer: Data on the fiscal soundness of HMOs are collected from two primary sources. First are the routine reports submitted through the National Data Reporting Requirements. These include operating statements, balance sheet and utilization information. Most HMOs submit the information on a quarterly basis. Those HMOs which are currently in a net surplus position are required to submit reports annually. Second are the annual audited financial statements prepared by an independent auditing firm. All information is submitted directly to the HMO program.

Question: Is there any attempt to verify the accuracy of the information?

Answer: There are several steps used to verify the accuracy of the information submitted by qualified HMOs. When reports are submitted to the HMO Office, they are verified for arithmetic and logical consistency. This is currently being done manually; however, when the computer system is fully operational, these checks will be done by computer. When errors are discovered, the compliance officer has responsibility for contacting the plan and making necessary corrections. If an HMO makes errors which indicate that the plan is unable to comply with the reporting requirements, this may justify a compliance investigation. As part of this consistency evaluation, there are the numerous checks and balances used in a double entry accounting system. Certain items which appear on balance sheets must also appear on operating statements and changes in financial condition statements. Therefore, it is possible to assure that the information is internally consistent.

The most reliable source of verification of the accuracy of information submitted by HMOs is through an audit performed by an independent accounting firm. All data submitted by an HMO throughout the year can be verified against the actual audited results. Significant variances between the audited results and those submitted on an interim basis by the HMO may justify a compliance investigation. We also have the authority to request an HEW audit to verify for ourselves the accuracy of the information being submitted. HEW audits have been requested in several cases for this express purpose. In addition, we have a contract in effect which provides us with skilled consultants who can audit the HMO's data system to determine whether it has the capability of collecting and producing the required data on a timely and accurate bases.

Certainly one area where we are cognizant of the regulatory red-tape burden on HMOs lies in the integration of paperwork requirements of states with those of the federal law. We felt that the first order of business should be improved coordination and integration within the executive branch itself. Discussions are ongoing with the Health Care Financing Administration to improve coordination of data requirements. We are pleased that the Office of Personnel Management (formerly Civil Service Commission) now utilizes our reporting requirements; operating plans may now submit the same information to the two agencies.

Unfortunately integration with state regulatory agencies is a much more difficult task. Each state has its own HMO laws and paperwork reporting requirements. These vary widely -- from minimal or non-existent requirements to reporting demands well beyond the federal government's. Particularly in executing compliance responsibilities, our objective is to integrate and coordinate information as much as we possibly can. Wherever practical we intend to utilize data provided to states. Sharing this information would ease the burden on HMOs, avoid duplicative (albeit not identical) requirements, and allow both the federal government and the state to have a common data base on the HMO. During this fiscal year we are undertaking a broad based inventory of the states to determine their actual reporting requirements and how these mesh with the federal government's. Clearly, we will have to negotiate agreements on an individual basis by state. We intend further to improve integration of state and federal reporting requirements wherever possible by working closely with the Association of HMO Regulators and the National Association of Insurance Commissioners.

HMO COMPUTERIZED WARNING SYSTEM

Question: I understand that the HMO office is in the process of implementing a computer program which will act as an early warning system for HMOs encountering financial difficulties.

When will that system be fully operational?

How will it affect the Office's need for staff in the Compliance Office once it is fully implemented?

Answer: We have already implemented the early warning system. The initial data base has been established and four diagnostic reports are routinely generated. We are continuing to expand the system with the expectation that it will be fully operational by June 1, 1979. The effect this system will have on the need for staff in the Division of Compliance is very difficult to measure at this time. We know that the system will allow the Division of Compliance to work much more efficiently by removing manual calculations and analysis from the duties of staff and putting them into the computer system.

HMO APPLICATION PROCESSING

Question: I have received some complaints over the past year that the HMO Office has promised to process grant or loan applications by a certain date and then has failed to meet those deadlines. My office has communicated with the HMO Office Staff on this problem.

What steps have you taken to alleviate it?

(Background: The Office doesn't have written procedures for all aspects of grant process, which could be resulting in arbitrary decision making).

Answer: You are correct; we have experienced excessive delays in the processing of grant and loan applications. However, we have studied the situation, identified reasons for delay, revised the review criteria, and implemented a new grant review process. Our goal is to complete the review of all applications within 120 days.

The previous backlog, in fact, has been eliminated and we intend all future actions to be processed within the established time frame. We have established specific steps and time deadlines for the processing of grants. Regional office staff have been trained in implementation of these procedures. We now have a tracking system to ensure that all grants stay on schedule and to identify grants falling behind.

In addition, the grant review criteria have been totally revised and updated. Loan applications are also being processed in 120 days or less and the backlog problem has been alleviated in this area as well.

HMO SITE VISITS

Question: To what extent have site visits to HMOs encountering financial difficulties been increased over the past year?

Answer: Implementation of a strengthened compliance capability over the past year resulted in a significant increase in the number of site visits to HMOs encountering financial difficulties. In the nine month period of October 1977 through June 1978, there were a total of nine compliance site visits. For the eight month period of July 1978 through February 1979, there have been 24 such visits. This would represent a 200% increase of visits on an annualized basis.

HMO SAVINGS

Question: Do you have any estimates on how much money the HMO program has saved the public in health care expenditures?

Do you have any estimates on how much government money has been saved by our investment in the HMO program?

Answer: HEW is just completing a study of the projects supported under Title XIII of the HMO Act between Fiscal Years 1971-1978 in order to determine the community cost savings associated with the 45 projects that became operational during that period. The Department will forward this study to you, as soon as it is available. Preliminary results, however, are now available, suggesting that:

- After ten years of operations, federally supported HMOs yield $2.70 in cost savings per each $1.00 of original federal investment.

- After 15 years of operations, federally supported HMOs yield $8.50 in cost savings for each $1.00 of original federal investment.

- The value of cumulative community cost savings due to all the HMOs (45) in our study, adjusted to the value of 1978 dollars are:

  - $250 million after ten years of HMO operation

  - $795 million after 15 years of HMO operation

Questions Submitted by Staff

ADOLESCENT HEALTH SERVICES

Question: Besides a $7 million supplemental requested in 1979, you have asked for an additional $53 million in 1980 for a new Adolescent Health Services Program. Would you please explain to the Committee how your office will go about implementing this program? (Maybe you could explain the steps that your office will go through in selecting sites for these projects, establishing the centers and obligating the $60 million)

Answer: The following plan has been developed for implementation of the program:

-- A grants management program will be developed. Procedures and materials will be prepared and disseminated to programs interested in applying for grants.

-- A committee will be established to review all proposals.

-- A management information system will be developed to enable the OAPP to effectively monitor programs funded under the statute. This system is currently in the developmental stage.

-- An evaluation plan is presently being jointly developed by the Office of the Assistant Secretary for Planning and Evaluation and the Office of Adolescent Pregnancy Programs.

-- A plan has been developed to provide technical assistance to prospective grantees as needed. Technical assistance teams will be established in eight sections of the country. Criteria for employment of technical assistants have been developed and recruitment is now taking place. The teams will be trained by OAPP and will be ready to assist programs in such areas as needs assessment, linkages of services, program development, evaluation techniques, proposal writing, organization structure, etc.

-- The OAPP is developing a plan to collect available data regarding incidence of adolescent pregnancy, low income areas, and services delivery systems now functioning through national sources (i.e. Census Bureau, National Center for Health Statistics, etc.,) the OAPP will request the information from State and local sources. Finally, in order to identify gaps in community services and assess project needs, the OAPP has developed a survey form to solicit presently unknown information. This plan will enable OAPP to make sound decisions regarding which areas best meet the funding priorities set forth in the statute (high incidence of pregnancy, low income area, few adolescent pregnancy related services).

-- A Public Information System has been established to disseminate information about the legislation. The system include speeches by the Director of OAPP interpreting the legislation to national organizations, State and local government officials, superintendents of schools, etc. These presentations include a slide series which visually describes the legislation and presents ideas to prospective grantees about various methods of service delivery. An OAPP Information Bulletin has been prepared and will be ready for press shortly. Several articles regarding the grants program have been written for publication in various national and local journals, and a "how to" manual will be prepared for use by the technical assistance teams and prospective grantees.

Site Selection, Establishment of Centers and Obligation of $60 million:

-- The legislation requires that priority be given to areas with high incidence of adolescent pregnancy, low income and few services. These areas will be determined following collection of the required data as described above.

-- The Program Development Division of OAPP, along with Technical Assistance Teams, will assist prospective grantees in program planning and development, planning of an evaluation component and related elements of the grant application process.

-- The Program Development Division and Technical Assistance Teams will assist in establishing the centers and provide continous monitoring of funded projects.

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-- Grants submitted for funding will be ranked according to how well they meet the funding priorities set forth in the statute.

Question: What will the 20 positions associated with this new program be used for and where will they be located? (How will this program be administered?)

Answer: The 20 positions will be administratively located in the Office of the Assistant Secretary for Health. The staff will:

-- Provide Departmentwide leadership for the planning, promotion, development, monitoring and evaluation of activities related to programs.

-- Develop requirements for grant approval, program regulations and national goals in coordination with related program efforts.

-- Implement and administer grants, including technical assistance and field and legal advice;

-- Provide liaison with the Office of Human Development Services, the Office of Education, other related Federal programs, private organizations and State and local government efforts;

-- Disseminate information to public and nonprofit private agencies and organizations seeking awards for community projects.

Question: How much of the $60 million will be used for non-recurring costs?

Answer: The budget request includes approximately $35,000 for supplies and equipment. The portion of that amount which represents non-recurring costs in 1981 will be channeled into grants and contracts funding.

NEW POSITIONS

Question: Last March, before the Committee on Human Resources' Subcommittee on Health, Mr. Champion testified that 37 new positions would be provided the HMO program, and virtually all of these for qualification and compliance activities.

How many of these positions have been filled?

How many pending qualification applications have yet to be reviewed and processed?

Answer: As indicated in response to a previous question, all 37 positions provided to the HMO program in 1978 by the reprogramming were filled. On March 14,1979, there were nine applications in active review in the program. Of these all are under 120 days old. Seven are in suspense status, because they are incomplete or because the applicant has requested that we delay consideration.

NATIONAL CENTER FOR HEALTH SERVICES RESEARCH

Question: There has been a great deal of controversy growing by both GAO and other members as well as the outside community that the National Center for Health Services Research has not been publishing research findings as mandated by Public Law 93-353.

We would like your comments on this. Could you give us some specific examples as to programs and items that you have in fact published and what impact or effect they have had?

Answer: As part of its dissemination effort, the NCHSR carries out an extensive publications program aimed at providing relevant research findings to those in need of timely information concerning health services research. The emphasis in these publications is on brevity and comprehensibility. Six different series of publications have been developed, each serving a different purpose. For example, the Research Digest Series offers an overview of an entire project, while the Policy Research Series provides a synthesis of the findings from a number of projects that address relevant policy issues.

More than thirty reports of special interest have been produced during the last year, with distributions ranging between 10,000 and 20,000 copies for a single document. These publications are routinely distributed to a wide variety of groups, including members of Congress, state and local government officials, health services research institutions, and dissemination workshop participants. A variety of publications are, of course, distributed at dissemination workshops. In addition, research reports are made available through the National Technical Information Service (NTIS).

Some NCHSR sponsored publications include the following: Controlling the Cost of Health Care; Analysis of Physician Price and Output Decisions; Drug Coverage Under National Health Insurance: The Policy Options; Impact of State Certificate-of-Need Laws on Health Care Costs and Utilization; and Demonstration and Evaluation of a Total Hospital Information System.

We believe that the rapid and effective dissemination of research findings is at least as important to a research program as the support of relevant and useful research projects. Moreover, it is equally important that relevant information be disseminated not only to the health services research community but also to the users of research, i.e., those involved in the organization, administration, regulation and delivery of health care programs and in the formulation and implementation of health policies. Prior to 1975, the NCHSR had depended, for the most part, upon the initiative of the researchers in getting their findings published in the scientific literature. That approach, however, clearly did not fulfill the needs of the users of research findings, such as the Congress, state and local government officials, as well as the various providers.

In 1978, NCHSR initiated a major effort to work with potential users of research results. This user community includes: state legislators and their staffs; governors and their staffs; state health directors and other state officials, as well as municipal

officials, involved in the operation of health care programs; the leadership of prepaid group practice plans, including those sponsored and operated by labor unions and industry; Health Systems Agency officials; major hospital directors, administrators and board members; and medical and other professional society representatives. These efforts are designed to emphasize the NCHSR's availability as a source of direct substantive assistance on critical policy and operational issues and problems, and to alert various user groups to the NCHSR's ability to serve as a conduit to the resources and expertise of the research community at large.

A major initial undertaking of this expanded dissemination effort has been the sponsoring of a series of dissemination workshops in various geographic areas, attended by potential users of research from within a particular area and focusing on concerns pertinent to specific geographic issues and problems and to the needs of leaders of the health care delivery system in these locations.

Such workshops are designed to: (1) establish rapport with users and potential users of health services research; (2) orient workshop participants to the NCHSR functions, activities, and available research reports; (3) disseminate relevant research findings; (4) provide a setting in which information vital to the operation and improvement of health care programs can be effectively communicated to non-specialists and lay persons; and (5) provide a forum for open discussion between those responsible for the delivery of health services and those conducting health services research.

As knowledge of this dissemination workshop program has increased, we have found a growing demand from the user community to co-sponsor and participate in these activities. In addition, our efforts have stimulated specific requests from individual workshop participants for information and assistance in areas pertinent to their particular needs and operational problems. In responding to these requests, the NCHSR provides information on NCHSR-sponsored research projects in specific areas of concern, gathers materials from relevant research being conducted outside the NCHSR, provides syntheses of major findings and issues, and facilitates the development of linkages between a particular user and the resources available from the research community at large.

For example, information and assistance has been provided at the request of various state legislators, particularly health committee Chairpersons, with respect to a broad range of issues, e.g., rate setting programs, both voluntary and mandatory, cost containment strategies, alternatives to long-term care, and drug product selection legislation. Various state health department officials have requested and received information and assistance with respect to issues and programs in the area of health promotion and disease prevention. Assistance has also been requested from various state health department officials with respect to mandatory evaluation of state generic drug substitution laws and the development of appropriate methodologies for evaluation.

The NCHSR's FY 1979 contract procurement plan calls for the development of two contract solicitations designed to disseminate

existing research information to state and local health leaders. One of these contracts will provide for the development and conduct of dissemination workshops on specific issues and operational problems identified by users as critical. The second will provide for an examination of the priority health policy issues and operational problems faced by the leadership of the health care delivery system within a particular state or states, and for the dissemination of relevant information on identified issues and problems to that leadership.

GAO REPORT

Question: GAO reported in June 1978 that of 13 HMOs evaluated, five have a fair chance of financial independence within five years, and six have a poor chance.

Can newly developed HMOs operate without continued Federal assistance?

Answer: HMOs which have been developed through the assistance of the federal government are gradually moving toward financial self-sufficiency. A lengthy process of up to five years is often required for the HMO to become self-sufficient. As reported on page 43 of the Annual Report to Congress, "Federally qualified HMOs are as a group moving in a positive financial direction. From 1975 when there were 41 plans in the Types 1 and 2 categories, the ratio of total income to total expense has increased from 72.5 percent to 90.6 percent. This is a trend indicating that those HMOs are moving toward financial self-sufficiency... Thus, despite adding many plans with low enrollment and fixed overhead, the total income of all HMOs has been increasing faster than the total expenses. For the seven Type 3 HMOs, as reported in their last annual report, the total income was greater than total expense by 1.5 percent."

Question: What measures can the department take to assure financial independence for HMOs in the future?

Answer: HEW has already initiated several administrative measures which strengthen the program's ability to assure that HMOs will become financially independent in the future. The Division of Development instituted prequalification review procedures to assure that HMOs reaching the stage of qualification fully understand the operation of an HMO and the requirements for qualification, including fiscal solvency. The process of qualifying HMOs has been significantly improved over the past twelve months. The Division of Compliance, through its early warning system, will have the ability to detect problems of a financial nature early enough to allow time for remedy. If an HMO gets into a serious financial condition, it is within the authority of the Compliance Division and the Loan Branch of the Development Division to take action to force changes in the operation of the HMO. Implementation and funding of the new technical assistance authority will be of help.

PROGRAM DIRECTION AND SUPPORT SERVICES

Question: What specifically are you doing within OASH to improve the administration of grants and contracts?

Answer: Within the agencies, structured systems are being installed in the contract offices. These systems will be monitored by staff of the Office of the Assistant Secretary for Health (OASH). The systems will insure timely and consistent reviews of reports, vouchers, and other contract submissions and will highlight the need for onsite monitoring or other special actions to correct deficiencies. Systems are now in place in CDC, FDA, and HSA, and they are in the process of being installed in the other agencies.

At this time, PHS is preparing to award a contract to obtain audit services in situations where problems are identified. These audits will be for both grantees and contractors.

PHS is requiring monitoring visits by grants management officers of all new grantees and most other grantees every 3 years. The purposes of these visits is to assess business capabilities and performance. In order to assist the grants management staff in performing these assessments, staff training is being provided. To date, approximately 600 PHS staff have received training.

PHS also has begun a major initiative to train all of its contract project officers by the end of fiscal year 1980. The training focuses heavily on project officer responsibilities in contract monitoring. By the end of fiscal year 1979, approximately 1,500 staff will have received this training.

Question: In the area of financial management, what are you doing to improve the management of PHS resources?

Answer: The PHS has taken a number of steps toward improving financial management activities. For example, PHS agencies have established achievable goals and developed plans for obtaining the goals which are reported on quarterly in connection with the Secretary's Management Initiative Tracking System (MITS) Financial Management Program. Through the means of monitoring the agencies' progress and by providing needed technical assistance, the PHS has made the following improvements:

- Reducing the number of vacancies in the Finance Offices.
- Reducing the time to pay vendor/contractor bills.
- Reducing the backlog of unreconciled control accounts.
- Reducing the error rate for input transactions.
- Reducing the backlog of uncorrected errors.
- Reducing the backlog of unclosed grants awards on DFAFS for most PHS agencies.
- Making documentation more current.

The PHS has recently developed a Financial Management Manual which will document and/or codify existing financial management policies and procedures as well as new policies as they are developed. This manual will provide guidance to PHS staff involved in any and all aspects of financial management.

In addition to PHS efforts, the Office of the Secretary has initiated the development of a new accounting system that can be adopted by all agencies with the Department. The system will be standardized and capable of processing all of the basic accounting transactions in HEW Also, it will provide better integration with other Department systems such as the Departmental Federal Assistance Financing System.

POSITIONS

Question: In last year's appropriation bill, the Congress specifically included staffing levels for the major health programs within the bill.

If we were program managers, would we be allowed to fill each and every one of those positions that is in the bill?

Answer: A program manager would not be permitted to fill each and every position because of the end-of-year employment ceiling which has been imposed on the Public Health Service. A program manager is expected to manage his level of employment in such a manner to assure that his employment ceiling is not exceeded on the last day of the fiscal year. It is recognized that during the year a manager may exceed his employment ceiling on a temporary basis because estimated turnover may not always occur as projected.

Prior to fiscal year 1979, the PHS has been able to fill at the end of the year approximately 97 percent of authorized full-time permanent positions. This 3 percent lapse rate is considered to be normal since it is very difficult to maintain employment equal to the total authorized position level at all times.

The Civil Service Reform Act of 1978 stipulates that the total number of federal employees be reduced to the September 30, 1977 level by September 30, 1978, and that level be maintained through September 30, 1981. In order to implement this Act, the end-of-year employment ceiling assigned to the PHS for fiscal year 1979 will permit a total employment level of approximately 95 percent of budgeted positions. The 95 percent ceiling has produced a savings in payroll costs for this fiscal year. These savings, which are estimated to be $12.6 million, have been used as an offset to the pay raise requirements of the PHS.

REGIONAL MANAGEMENT

Question: Your justification mentions a "realignment of the operational functions" of regional management. What does this refer to--another reorganization?

Answer: The realignment of operational functions referred to changes in duties and responsibilities of the Regional Health Administrators.

Question: How did you determine that this would result in the need for one less position in each regional office?

Answer: The realignment of the operational functions of the regional offices relieved the Office of the Regional Health Administrators of some of the duties and responsibilities for health planning and health resources development. It is anticipated that with continued emphasis on efforts to reduce costs this will permit the reduction of one position in each of the ten regions.

INTERNATIONAL HEALTH

Question: You are requesting a sizable increase of $2.2 million for your Office of International Health. What tangible results are expected to be realized from this investment?

Answer: Results are expected from investment in five principal areas: private sector involvement in international health, development of multi-donor consortia, the U.S.-Mexico Border Health Initiative, policy-related studies, and the development of an international health information system in the Department.

One of our objectives is to mobilize more fully the resources of the U.S. private sector in meeting U.S. international health goals. Each year private institutions, including the churches and foundations, spend millions of dollars for international health activities. In order to avoid duplication of effort and achieve our international health goals more rapidly, we are planning to spend a portion of the $2.2 million to develop and implement mechanisms for coordination of Federal and private sector efforts in international health.

A somewhat analogous situation exists with respect to donor support of the programs of the World Health Organization (WHO). WHO is dependent on extra-budgetary resources to achieve its goals. Currently, a variety of donors, including governments and private organizations are spending vast sums on health and related programs. Adequate mechanisms do not exist for focusing these resources on important WHO goals, many of which are quite new. It is important to the United States, in terms of achieving our international health objectives, that this donor support be effectively mobilized. To meet this need, we propose to use funds in 1980 to facilitate the creation of multi-donor consortia to focus on these important health goals.

We are curently developing a program with Mexico, focused on border health programs, which will produce tangible results for both countries. One outcome will be a coordinated, mutual epidemiologic surveillance system for communicable and chronic diseases, drug abuse, and family planning. An important benefit of such a system will be advance notice of communicable disease problems advancing toward the border from Mexico and other parts of Latin America.

Funds requested would be used for policy studies related to our relationships and involvement in multilateral organizations and bilateral program activities. Our present involvement is substantial, involving activities with 23 countries and includes a new program with China. We are continually dealing with policy

questions in these relationships, and in order for us to deal with these issues adequately and to make appropriate decisions, these policy studies must be undertaken.

We do not have an international health information system within the Department. A system is needed if we are to know the full extent of what we are spending for international and related activities. The system would provide us with the data base needed for planning our programs better, including use of resources, evaluation, and coordination both within the Department and with other departments and agencies.

WASHINGTON OFFICE

Question: I understand the National Center for Health Services Research is funding several centers around the country. Some of those centers have established Washington, D.C. offices.

Given the fact that the National Center is already here, can you explain to us why it is necessary to have such offices?

For the record, provide what the cost of these offices are.

Answer: One national "special emphasis" center has a Washington, D.C. office, and that is the Health Care Policy Analysis Center located at the University of California in San Francisco. The reports which accompany the legislation mandating a research centers program speak directly to the issues of having these centers independent. If a research center believes that it can better carry out its responsibilities by having a particular organizational arrangement, then that center has the responsibility to do what it believes to be in the best interest of the program. Since the Health Services Policy Analysis Center is expected to respond to the needs of the Federal government, this center has established a Washington office to more effectively deal with the Congress and the Department. The cost of the office is approximately $87,000, with a staff of four people and one consultant. The office is responsible both for expediting communication with the Congress and the Department and for the conduct of the policy analysis and research syntheses as they are requested. The center in San Francisco is responsible for the detailed and longer range analyses and for providing the essential expertise as required by particular requests.

Question: For the record, please tell us how much money in terms of staffing years and dollar costs were spent on developing your Zero-Based Budgeting proposal this year and your mission budgeting program.

Answer: The Public Health Service estimates that 126 man-years of effort and $3.2 million were spent in the development of

the 1980 Zero-Based Budget (ZBB). Approximately one man-year and $29,000 were spent to develop the mission budget.

The mission budget does not appear to represent a significant workload. After all of the final decisions are made on the President's budget from the ZBB presentation, the mission budget is developed from data included in the ZBB material. It should be understood that staff effort and related costs attributable to ZBB do not represent incremental costs. The majority of the costs incurred in the ZBB process would be expended no matter what system of budgeting was used.

ADOLESCENT HEALTH SERVICES

Question: What procedures have been developed for review of grant applications?

Answer: A grants management program will be developed. Procedures and materials will be prepared and disseminated to programs interested in applying for grants. A committee will be established to review all proposals.

Question: What emphasis will be placed on the funding of preventive programs, i.e., those based in educational or family planning agencies?

Answer: Legislation specifically requires that as part of 'core services' grantees plan for the administration and coordination of pregnancy prevention and pregnancy related services such as family life and sex education programs.

Question: How will you ensure that all grantees comply with the pregnancy counseling language of the legislation--specifically that adolescents are informed of the availability of abortion counseling and are offered a referral?

Answer: A management information system will be developed to enable the OAPP to effectively monitor funded projects to ensure that they comply with the "counseling language" of the legislation.

Question: The sudden influx of $60,000,000 in OAPP would present the office with a tremendous challenge to ensure the effective expenditure of these new monies. Can programs for pregnant adolescents and adolescent parents expand so rapidly?

Answer: Preliminary proposals have been received from approximately 75 private and public organizations. This high level of interest has been expressed even prior to issuance of proposed rules. It is anticipated that requests from communities throughout the United States will more than triple after issuance of the Proposed Rules. The proposals that have been submittted thus far have been well developed and show an understanding of the issues involved. This indicates that there will be little difficulty in effectively using the fund when available.

Question: What priorities have been established for the expenditure of these funds?

Answer: The legislation requires that priority be given to areas with high incidence of adolescent pregnancy, low income and few services. These areas will be determined following collection of the required data. Grants submitted for funding will be ranked according to how well they meet the funding priorities set forth in the statute.

Question: Have some communities been designated priority areas for grant awards on the basis of the incidents of adolescent pregnancy and the unavailability of services?

Answer: The OAPP is developing a plan to collect available data regarding incidence of adolescent pregnancy, low income areas, and services delivery systems now functioning throughout the country. Where necessary information is not available through national sources (i.e. Census Bureau, National Center for Health Statisticsm etc.,) the OAPP will request the information from State and local sources. Finally, in order to identify gaps in community services and assess project needs, the OAPP has developed a survey form to solicit presently unknown information. This plan will enable OAPP to make sound decisions regarding which areas best meet the funding priorities set forth in the statute.

Question: What balance will be struck between funding existing and new programs?

Answer: Since the legislation is flexible the OAPP plans to give priority to the areas of greatest need. The over 3,000 letters and 75 proposals that have already been submitted to OAPP indicate the extent of the need and the readiness of communities and organizations around the country to apply for grant monies to expand the their existing services to include core and supplemental services which many programs now have in place in fragmented form. The funding make linkages among these existing services and provide new services where none now exist. This linking of services is the key factor in the success of such programs. Many of these programs have been in existence for a number of years but have not had the funding to make such linkages.

Question: It is almost a year since Dr. Lulu Mae Nix came to HEW and over four months since her swearing in as Director of OAPP. Would you describe what has been accomplished by that Office in that time.

Answer: Because no funds have been appropriated for the Office of Adolescent Pregnancy Programs, the Office has had to operate with only a Director and consultants. Even though it has had no regular staff, the Office has accomplished all assigned tasks, including the following:

-- Preparation of proposed Regulations for Title VI of Public Law 96-626;

-- Development of an organizational plan, establishment of goals and priorities;

-- Responded to 3,000 letters, telephone calls and personal visits from individuals and public and private agencies from all sections of the country; requests for information from Congress, and queries from the media the country;

-- Received and analyzed approximately 75 preliminary proposals from public and private non-profit organizations;

-- Worked with officials in various States and cities to encourage the development of coordinating committees to help develop statewide or citywide plans for delivery of adolescent pregnancy services;

-- Developed an Information Bulletin for national dissemination describing the legislation and functions of OAPP, to be sent to governors, mayors, Chief State School Officers, school boards, national and local organizations, etc.

-- Prepared a plan for a comprehensive technical assistance program to be administered by OAPP; developed criteria for recruitment and employment of qualified technical assistants, and developed plan for staff training.

-- Established an inter-agency research committee to coordinate all research on adolescent pregnancy within the Department; and planned a mechanism for coordinating adolescent pregnancy programs within the Department with representation from appropriate agencies.

-- Developed procedures for development of a grants management program, a management information system; worked with the Office of Assistant Secretary for Planning and Evaluation on development of an evaluation plan for Title VI of the statute;

Made numerous site visits in various States to review alternate models of service delivery systems and identify services delivery needs and problems; and provided technical assistance to prospective grantees as time permitted.

Question: What is the status of the Regulations?

Answer: The OAPP has completed the proposed Regulations which have been approved by appropriate members of the Department and signed by the Secretary. They are scheduled to be printed in the Federal Register within the next few days.

Question: In what respect do they amplify the legislations?

Answer: Because the statute is extremely explicit in many areas and in order not to limit further the flexibility of grantees to devise innovative approaches to providing services, many of the statutory provisions in the regulations have been repeated. However, some additional guidance, such as statistical information required from applicants for grants, has been provided in the proposed regulations and additional program guidance will be issued by the Secretary.

Question: Is there an evaluation plan for the program?

Answer: An evaluation plan is now being developed by the Office Planning and Evaluation, PHS, the Office of the Assistant Secretary for Planning and Evaluation and by the OAPP.

Question: What are its overall objectives and major features?

Answer: The plan will include three components progressing simultaneously:

-- Projects will report on progress against certain management objectives, i.e the numbers and types of adolescents served, the proportion of teens in the community receiving primary prevention services, the proportion of pergnant girls receiving comprehensive services as required by statute, number of referrals to other agencies, etc.

-- Projects will report on, and be evaluated locally against a few selected national outcome objectives, i.e. number of initial or repeat pregnancies among those served, changes in health status of those served, number remaining in or returning to school, number of adolescents who keep their babies on welfare, etc.

-- National evaluation of program impact and what sort of projects work best and why. Impact evaluation would compare like communities with and without projects as to incidence of pregnancy, health status of adolescents and their babies, school dropout rates, number on welfare, etc. This will include a longitudinal study of program participants and non-participants. Evaluation of what works best would be and by comparing certain projects with certain components (perhaps randomly added) against projects in similar communities without these components.

NEW PROGRAMS IN THE OFFICE OF THE ASSISTANT SECRETARY

Question: Dr. Richmond, you have several new programs within your office.

Why was it decided to include these programs in your organization, rather than locating them within the various agencies of the Public Health Service?

Answer: The new programs placed within my office are those which are of high priority and warrant special emphasis. The responsibilities of these programs are cross-cutting in nature and the activities must be coordinated with a variety of other organizations. The implementation of these activities is a vital element of their success and this can best be handled within the Office of the Assistant Secretary for Health.

HEALTH INFORMATION AND HEALTH PROMOTION

Question: What specific activities will be supported by the $3.6 million increase requested in 1980 for health information and health promotion?

Answer: During FY 1980 the specific activities for the Office of Health Information and Health Promotion will include full operation of the National Health Information Clearinghouse, development of a media campaign for health promotion and coordination of studies related to health risk assessment.

The National Health Information Clearinghouse will become fully operational as a switching center for information requested in the course of the National Health Promotion Program. It is anticipated that with the release of the Surgeon General's Report on Prevention there will be increased public awareness and interest in health promotion efforts, placing an even greater demand on the Department for health information. Other activities of the Office which support community health promotion efforts will benefit from the expanded scope that the Clearinghouse will experience. The Clearinghouse will provide a depository of health information for communities and will promote the exchange of this information with other communities. It will be a one-stop center which will assist the public in seeking current and accurate health information. The Clearinghouse will also assist providers of health care by giving them ready access to updated health information for providing better service to those whom they serve.

A recently released draft of a proposed report of the General Accounting Office notes extensive duplication of bibliographic information systems in both the Federal and private sectors. The report also indicates that the lack of a single source of comprehensive information may contribute to duplication of efforts. One of the primary functions of the National Health Information Clearinghouse will be to serve as a comprehensive source of information about other health-related resources, both within and outside the Federal Government. The Clearinghouse will promote these resources through a variety of media and, thereby, increase awareness of their existence and services. Furthermore, the Clearinghouse will provide a forum and serve as a catalyst for the exchange of information among health information providers. Thus, this Clearinghouse will build a network among the currently fragmented health information resources and providers, thereby increasing long-term savings and reducing duplication of efforts.

Also as a key to the success of the National Health Promotion Program is the carefully planned use of television and radio to heighten public awareness with respect to measures each individual can take to improve health. This use of the media will build on and expand those efforts initiated in FY 1979 and will emphasize integrating personal approaches to reducing the risk of disease through better nutrition, smoking reduction, more exercise, and better hypertension control. Mass media can be a valuable adjunct to other forms of preventive intervention because it is particularly effective in altering people who are in high risk groups. The potential of health education with mass media seems great but remains

largely unsystematic and unevaluated. Activity of the Office will be to both maximize and assess the impact of media efforts in the area of health information and health promotion.

Another area of activity will be the development of studies related to health risk assessment which will: (1) identify significant individual characteristics which impact on or reflect health, identify the impact, and assign scores to such characteristics; (2) test a variety of motivational messages to be included in the risk assessment and/or precede or follow it; and (3) determine the most effective manner for structuring questions to elicit accurate and useful responses. The completion of the above activity will result in development of far more accurate methods of predicting individual risk of morbidity and mortality. Such predictions form the basis for personally-tailored programs to reduce risks and may provide participants with the impetus to adopt and maintain risk reducing behavior. In the long-term, widespread dissemination of risk assessment instruments can bring awareness of the preventable nature of illness to people everywhere since their use is not limited to medical settings.

NATIONAL MEDICAL CARE UTILIZATION AND EXPENDITURE SURVEY

Question: You are asking for $2.9 million increase for your national health survey and analysis program to initiate a MCUES in conjunction with HCFA.

a. How much will HCFA contribute to effort?

b. If resources are appropriated in 1980 when can we see results from the survey?

Answer: a. The National Medical Care Utilization and Expenditure Survey is planned as a continuous survey of the civilian population of the United States. Each cycle of the survey will require approximately two years for data collection. The total cost of the 1980-81 cycle of the National Medical Care Utilization and Expenditure Survey, including the funds provided by HCFA to supplement the survey for their particular needs, and start-up costs for the 1982-83 cycle is $17.3 million. Estimated funds from NCHS and HCFA by fiscal year are:

	FY 79	FY 80	FY 81	TOTAL
		($ in Millions)		
HCFA	$ 2.9	$ 5.6	$ 3.0	$ 11.5
NCHS	---	2.9	2.9	5.8
TOTAL	$ 2.9	$ 8.5	$5.9	$ 17.3

b. Data tapes from a sub-sample of the Survey will be available in mid 1981 and preliminary results will be published in late 1981. Data from the completed survey including the followback contacts with health care providers will be available in 1982.

PROMOTION OF HMOs

Question: Do you have information on how many employers now offer their employees the option of joining a qualified HMO?

Answer: Neither the federal government nor any private organization is collecting data on the total number of employers now offering the HMO option.

Question: How much support has the private sector provided for HMO development?

Answer: Historically, some of the most successful HMOs have developed without federal financial assistance. Examples include the Kaiser-Permanente Health Plan (industry sponsorship), Group Health Cooperative of Puget Sound (consumer sponsorship), and the Harvard Community Health Plan (university sponsorship).

The HMO Act of 1973 provided federal funds for HMO development for applicants who demonstrate that they can't complete development without federal financial assistance.

The private sector has, therefore, played a significant role in HMO development. However, many programs require federal financial assistance and without that assistance HMO growth would be much slower.

Since the Secretary's National HMO Conference on March 10, 1978, we have seen a considerable amount of additional private sector support for the HMO concept particularly among business and labor, but also among physician and consumer groups. For example, fifteen large corporations including Ford, GM, Chrysler, DuPont, John Deere, Monsanto, and several large insurance companies are developing HMOs or looking at HMO feasibility. These efforts are proceeding without federal fostering. We know of many multispecialty fee-for-service group practices that either have considered or are currently contemplating HMO development. Some of these will not require federal funding.

HMO growth over the next several years will require a mix of private and public funding. The HMO staff in our regional offices are currently surveying private HMO development efforts. Nationwide estimates will be assessed in late April. The federal government has, we think, a responsibility to stimulate private investment while providing federal financial assistance to the sponsors who cannot obtain private funding.

Question: How has the administration encouraged the expansion of HMO activities through means other than HMO legislation?

Answer: Wherever possible, we like to encourage HMOs to undertake expansion using private capital rather than federal funding provided under the legislative authority in Title XIII.

Experience to date, however, indicates that for the most part HMOs seeking to expand are nonprofit organizations operating in a deficit financial position who find it difficult to get private capital for their expansion activities. HEW supports the use of federal funds for expansion because in addition to bringing the benefits of HMOs to greater numbers of citizens, we think that it is a cost effective use of federal dollars. By building on the base of existing HMOs we substantially reduce the risk of development failure. Moreover, because staff and management are in place, costs and development time should be lower and new enrollment can begin without a substantial start-up deficit. As indicated above, we intend to continue to encourage greater private investment in expanding HMO activities nationwide.

Question: What efforts have been made to encourage HMO development in medically underserved areas?

Answer: We are anxious to encourage development of HMOs in medically underserved areas. As you know, development of HMOs in these areas is a priority under the HMO Act.

We have a legislative requirement of a 20% set aside for specific funding of HMOs in rural areas. In fiscal year 1978 about 10% of our grant funds went to projects in non-metropolitan areas. We were unable to identify sufficient numbers of qualified organizations to meet the full 20% set aside. Historical experience tells us that it is often difficult to start an HMO in these areas because of the small population base, frequent lack of adequate income levels, and absence of large employer groups. As a consequence, there often is less interest in HMO development in rural areas. Nevertheless, we are trying to encourage this interest. For example, recently we sponsored a conference on rural HMO expansion with the Caldwell B. Esselstyn Foundation in upstate New York. Representatives from health plans nationwide came to this conference to discuss and formulate the best means of expanding their operations into counties and towns which are medically underserved rural areas.

The health services amendments of 1978 (P.L. 95-656) provide encouragement to growth of prepayment in medically underserved areas. The authority would allow community health centers, migrant health centers and HURA projects to convert partially to prepayment in their operations. Some of these projects have the potential of meeting the requirements in Title XIII including hospitalization coverage. If these projects intend to become qualified HMOs from the outset, we insist that they seek funding under Title XIII. If, however, operational projects seek partial conversion over the long term, they may choose to use this new authority as a bridge. This authority does provide encouragement to growth of prepayment in medically underserved areas.

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NATIONAL CENTER FOR HEALTH STATISTICS
AND OTHER HEW PROGRAMS

Question: How does NCHS serve other DHEW programs?

Answer: For many years the general purpose descriptive health data produced by the NCHS has been used by other DHEW programs to identify health problems and to set program priorities and allocate resources to address those problems. The NCHS has worked directly with those programs to identify their data needs for program planning and evaluation.

In 1970 the Congress authorized the development of the Cooperative Health Statistics System (CHSS) to meet multiple needs for health data by local, State, and national agencies. In 1974 and again in 1978, Congress strengthened the mandate of the System and required its implementation. The NCHS has been developing this System in conjunction with other HEW programs as well as public and private agencies at the State and local levels to meet the data needs of these various agencies without duplicate data collection. For example, the Health System Agencies (HSAs) funded through the Bureau of Health Planning, look to the CHSS as their primary data source to meet their legislatively mandated planning activities.

A third major activity of the NCHS which has been developed to directly serve the needs of other DHEW programs is the Reimbursable Work Program. Through this Program other agencies can request services on a cost reimbursement basis from NCHS for the conduct of statistical activities such as the conduct of special surveys or analyses, supplementing on-going NCHS surveys to obtain specialized information, or obtaining technical assistance in survey design, questionnaire development, quality control procedures, etc. Since the inception of this program in 1976, the demand for services by other DHEW programs has been quite high since these programs are able to obtain services more quickly and much cheaper than if they contracted with the private sector. Additionally, the program provides us with an excellent method to better coordinate the data activities throughout the Department. To date, NCHS has carried out work through reimbursable agreements for:

- National Institute on Alcohol Abuse and Alcoholism
- Environmental Protection Agency
- Bureau of Community Health Services
- Food and Drug Administration
- National Institute on Drug Abuse
- National Institute of Neurological and Communicative Disorders and Stroke
- Bureau of Health Planning
- Health Care Financing Administration

- National Institutes of Arthritis, Metabolism, and Digestive Diseases
- Indian Health Service
- Health Services Administration
- National Cancer Institute
- National Institute for Occupational Safety and Health
- National Institute of Child Health and Human Development
- Veterans Administration

Question: How are data needs determined and how are collection efforts coordinated?

Answer: Needs for health data are determined through a variety of continuing methods. Primary among these is the statutorily mandated role of the National Committee on Vital and Health Statistics to advise the Secretary on statistical problems bearing on health and health services and to stimulate studies of such problems. This Committee recommends specific data items, quality control procedures, etc., which are then widely promulgated throughout the Department, schools of public health, and the health care delivery system components, for review and comment. After appropriate revisions and field testing the data sets are endorsed by the Department.

The NCHS also maintains a number of interbureau and interagency committees and task forces to keep abreast of program plans which may require new data collections or analyses.

The NCHS maintains contact with the health professional associations and organizations which provide a continuing input into the assessment of data needs.

Additionally, the individual survey programs of NCHS solicit direct input into survey content from a wide variety of persons and organizations as survey content is decided upon.

With respect to coordination of data collection activities, in the past year we have taken a number of steps to insure better coordination. Specifically:

- The recent reorganization in the PHS created the Office of Health Research, Statistics, and Technology which serves as a central locus for the development and coordination of health statistics within the PHS.
- The PHS Health Statistics Coordinating Committee, chaired by the Director, NCHS, is charged with the review of all PHS health data activities for possible duplication and compatibility with existing data collection and analysis

efforts. It has already adopted certain uniform data items and definitions to be used in all PHS reporting systems.

- A new PHS Task Force on Cost of Illness, chaired by the Director, NCHS, has been established to systematically review cost of illness activities in the PHS and develop methodological guidelines so that the results of different studies will be comparable.

- The Department of Health, Education, and Welfare Health Data Advisory Committee reviews departmental data activities for possible duplication, feasibility, data gaps and comparability. It is chaired on a rotating basis by the Associate Administrator for Policy, Research, and Statistics (HCFA) and the Deputy Assistant Secretary for Health Research, Statistics, and Technology (PHS). The Director, NCHS, is a member of the Committee.

- The National Committee on Vital and Health Statistics was continued under Public Law 95-623 and advises the Department on matters relating to standardized means of data collection, minimum data sets, standards for data quality, and other activities related to the standardization and coordination of departmental statistical efforts.

- The NCHS Reimbursable Work Program allows other agencies to utilize NCHS expertise and existing data collection mechanisms to obtain needed health data and thereby reduce respondent burden and duplicative, noncomparable reporting systems.

- NCHS has entered into some interagency agreements to jointly sponsor data collection activities or agree on spheres of interest that reduce duplication and result in coordinated efforts. Examples are the Medical Care and Utilization Expenditures Survey, jointly planned and funded by NCHS and HCFA, and an interagency agreement between NIMH and NCHS regarding collection of mental health statistics.

Question: Does the data collection activities of NCHS duplicate the efforts of other HEW programs?

Answer: No, they do not. We have a number of coordinative mechanisms to insure that the statistical activities of the other PHS health programs are complementary and consistent with the overall health data strategy of the Department and the programs of the NCHS are the cornerstone of that strategy.

HEALTH CARE TECHNOLOGY

Question: Would you please describe the activities planned for your new National Center for Health Care Technology?

Answer: The National Center for Health Care Technology (NCHCT) will coordinate the efforts of all HEW agencies in the technology area and serve as a focal point within DHEW for technology-related issues. Specifically, Section 9(c) of P.L. 95-623 authorizes the following activities:

1. undertaking and supporting (by grant or contract) assessments of health care technology. These assessments will take into account the safety, effectiveness, and cost-effectiveness of health care technologies, as well as their social, ethical, and economic implications;

2. encouraging, undertaking, and supporting (by grant or contract) research, demonstrations, and evaluations concerning: the factors that affect the use of health care technologies in the United States; methods for disseminating information on health care technologies; and the effectiveness, cost-effectiveness, and social, ethical, and economic impact of particular technologies;

3. encouraging and supporting (by grant or contract) research, evaluations, demonstrations respecting the safety and efficacy of particular health care technologies;

4. make recommendations to the Secretary respecting health care technology issues in the administration of laws under the Secretary's jurisdiction (e.g., Medicare), including recommendations with respect to reimbursement policy for specific health care technologies or classes of technologies;

5. assist public and private nonprofit entities in meeting the costs of establishing, or operating extramural centers to carry out assessments and research, in the area of health care technology;

6. undertaking and supporting manpower training programs to assure a supply of individuals qualified to perform research in the area of health care technology.

The Center will provide HCFA with the best available scientific and economic evidence on which HCFA can make decisions regarding payment by Medicare for specific health care technologies or classes of technology. The informal manner in which this evidence has been developed in the past has become inadequate as the rate at which coverage inquiries being raised by Medicare intermediaries has increased. The newly created NCHCT will improve the ability of PHS to handle the larger number of more complex coverage questions posed by HCFA and will increase the sophistication of the criteria upon which coverage advice is developed.

The Center will also work to improve the dissemination of information on new technologies: To promote the transfer from

research to practice of appropriate new technologies; to retard the transfer of questionable new technologies; to identify the practice of inappropriate procedures and uses of inappropriate technologies; and to stimulate the development of promising technologies.

The Center will pursue an active communications policy to better inform PSROs, health planning agencies, academic and specialty groups, and the practicing community about developments in the technology area.

DIVISION OF RESEARCH GRANTS

Question: Dr. Richmond, in the last four years, staffing for the Division of Research Grants which reviews all grants at NIH, has dropped by four positions.

On the other hand, the number of grants received by NIH has grown from 9,000 to 18,000.

Would you please tell us how they are doing the job?

In effect, aren't we asking for slowness in terms of being responsive to grantees and also abuse and mismanagement as well without having more people doing the job?

Answer: The permanent full-time position ceiling of the Division of Research Grants (DRG), which was 377 in FY 1974 and 1975, was increased to 397 in FY 1976, reduced to 381 in FY 1977, and in FY 1978 was set at 400. I emphasize that these figures are employment ceilings and not on-board strength. During the course of any year, gains and losses are experienced on a continuing basis which naturally result in deviations from the position ceiling. Under any circumstances, however, the DRG has been confronted essentially with a doubling of workload without a concomitant significant increase in personnel.

The Division has managed to cope with this situation only with considerable difficulty and through a remarkable degree of devotion to duty on the part of its own staff of professional, technical, and clerical employees and the generosity, cooperation, and dedication of nearly 800 consultants who are non-Federal employees and who in total comprise the membership of the Division's study sections or initial peer review groups.

To date, no slowness in responsiveness to applicants or grantees has been experienced. The Division continues to observe its receipt and review cycle whereby new applications received by February 1 are reviewed by study sections in June, applications received by June 1 are reviewed in October and November, and those received by October 1 are reviewed the following February and March. I can say without reservation, and I am confident that Dr. Fredrickson would agree, that there has been no evidence whatever of abuse or mismanagement. In the face of this enormous increase in workload, however, and because both the employees and the consultants continue to work within the same finite time frames, maintaining the quality of review has become extraordinary difficult. For example, four or five years ago a particular study section with a membership of 20 consultants may have been required to review 95 applications within a three-day period. Today, the same study section with the same number of members may be required to review 200 applications.

PUBLICATION SCHEDULE OF THE NATIONAL CENTER FOR HEALTH SERVICES RESEARCH

Question: My Office has received numerous complaints regarding the inordinate delays in publication of research results by NCHSR. While timely publication is essential, I have received allegations that the time lag at the Center is well over 6 months for most publications.

Describe the process for publication of a research report once it is submitted to the Center.

Answer: We would like to begin by providing background information about all NCHSR publications.

The NCHSR research program during the past year has consisted at any one time of about 230 grants and from 16 to 30 contracts. These figures change as new awards are made and research projects end. Each research project results in at least a final report, and may also yield journal articles, interim reports, and special reports such as state-of-the art reviews.

All final reports are made available to the public by the National Technical Information Service, U.S. Department of Commerce. During the last fiscal year, for example, NCHSR sent to NTIS about 170 reports, 30 papers, 4 data tapes, 14 series reports, and 1 thesis. No effort is made to capture the journal articles resulting from NCHSR research support, but open literature publishing is extensive.

In addition, NCHSR selects reports for special publication. These decisions to publish are based on relevance to key issues, and to demand for information on particular topics.

From mid-1976 to present, more than 90 publications in six different publication series have either been issued or are in preparation. A single report may be printed in amounts up to 20,000 and be exhausted in two years. Telephone, mail and personal requests for NCHSR publications have increased tremendously. Mail requests average about 100 each work day. Further, distribution of NCHSR publications at annual meetings, such as the American Public Health Association, are in excess of 14,000 individual copies per meeting. NTIS sales to the public, resulting from their extensive public announcement of available publications, amounts to several hundred copies for each title.

In order to make research users and potential users more aware of NCHSR products, a news announcement operation has been initiated. The news announcements contain one-paragraph descriptions of research accomplishments, notable research applications, and key findings. These are written in newsletter style and are specifically directed toward the 100 or so newsletters, journals, supplements, and other publications in the health services delivery area. Publication of these announcements contributes to mail requests for copies of publications.

Since mid-1976, nearly one million copies of NCHSR publications have been put in the hands of readers.

The process for publication of a research report by the Center begins with peer review of the report or manuscript, recommendations to publish by the project officer and Division Director, and clearance and approval to publish as a center report by the Director, National Center for Health Services Research.

A DHEW publication concept clearance is obtained, the manuscript is prepared for printing, including graphic art, and sent to OASH Printing Management.

Question: What are the time frames that employees are required to meet at each stage?

Answer: There are no specified time frames that employees are required to meet in this process, although because the staff is so small it is often necessary to set priorities among publications.

Question: Provide a listing of the time frames for each report published by the Center in 1978. In any case where publication time exceeded 6 months summarize the reasons for delay.

Answer: The time frames for the various research reports that were issued as publications in the last year (excluding time for peer review of drafts and rewrites by investigators) ranged from 6-12 months, depending upon how extensively they had to be rewritten and edited by NCHSR, how many manuscripts were being worked on at any one time, and the backlog at the G.P.O. contract printer. In 1978 NCHSR experienced two new problems, a national paper shortage that affected the contract printer and an appropriation delay that resulted in a number of printing jobs being held up.

While this question does not pertain to conference reports, we wish to state that last year it was not uncommon to have these larger manuscripts in the contract printers shop for more than 3 months (in one instance for more than 120 working days) after all staff work had been completed.

Question: Has the Center experienced inordinate delays in obtaining peer review of research results? What steps has the Cneter taken to speed the peer review process?

Answer: Peer review of research results is not a problem. There have been no delays. However, review of reports frequently results in extensive rewriting, both by outside investigators and by members of NCHSR staff.

One reason for this is an attempt to publish policy relevant research reports in language that can be understood by non scientists who use research results.

Question: One area that is of particular concern is the publication of conference proceedings. I have received allegations that even when a conference chairman has edited the proceedings and received approval of all of the authors involved, that publication delays of 6 months or more are not uncommon.

Describe any differences that exist in the approval system for conference reports as opposed to research reports.

Answer: Unlike research reports, Conference proceedings are not peer reviewed, as the conference process itself is regarded as performing this function. The decision in both cases, of whether to print as an NCHSR publication is made internally.

Question: I have been informed that a 2 month time-frame is sufficient for publication of these types of reports. Do you agree? Why or why not?

Answer: Two months is not time enough for a conference proceeding. Usually these are quite large (200 to 350 pages) jobs. Transcribing, editing, and obtaining authors' approvals, often takes more than two months. Technical review is then performed by NCHSR staff. After approval by the Director, NCHSR, the final editing, printing, and distribution process begins. Frequently there is extensive layout and format involved. NCHSR is supported by a single graphics artist, who shares his time with this Center and the National Center for Health Statistics. These jobs are so large that the G.P.O. contract printer sometimes delivers proof in batches. The editor, conference chairman, and authors must be sent proofs of galley, page, and any intermediate stages.

Few unavoidable delays have been experienced on work performed inhouse. Major delays have been experienced with the printing process itself. It should be noted that NCHSR does not have direct contact with the G.P.O. printing contractor.

Question: What steps are you taking to improve the timeliness of publication?

Answer: An additional person has been assigned to part time editorial duties and recent change in printing contractors is expected to help avoid delays. A management assistant has recently been assigned to the publications function to assist with the approval, tracking, and logistical aspects of publications printing, and is expected to assist particularly in dealing with outside offices.

FRAGMENTATION

Question: Last year, in addition to cutting the Health Practices Assessment Practices Program out, the Committee and the Conferees also agreed to begin the elimination of many of the special interest programs within the Office of the Assistant Secretary for Health. Tell us how this phase-out is being completed and what you are doing with the programs and people.

Answer: The offices involved have been phased out and the employees have found other employment on their own or through internal placement programs.

Question: In June, GAO submitted a report to Congress entitled "Legislation Needed to Encourage Better Use of Federal Medical Resources and Remove Obstacles to Interagency Sharing." In essence, they were critical and said that the Government can make much better use of its health care delivery resources through interagency sharing.

What are you doing to do a better job in this area and how are you responding to this GAO report?

Answer: The Department concurred with the GAO recommendations which state that the Secretaries of Defense and HEW and the Administrator of Veterans affairs jointly direct the Federal Health Resources Sharing Committee (FHRSC) to seek workable solutions to the administrative obstacles within each agency which impede sharing and report annually to the appropriations committees on the progress being made in implementing an effective sharing program.

We believe the FHRSC is making progress in implementing an effective sharing program. As a result of the committee's formal and informal discussions on sharing opportunities, five subcommittees have been established in the following areas: Cardiac Catheterization Laboratories, Computed Tomography, Dental, Medical Information Systems, and Cancer Treatment Centers. The establishment of a sixth subcommittee, Mobilization Support, has been deferred until July 1979. Presently, the active subcommittees are developing interagency standards to identify and promote opportunities for joint planning and use of resources. Site visits also are being conducted for assessment, and recommendations are being made involving interagency sharing.

Upon completion of the subcommittees' studies, their recommendations are provided to the committee for its evaluation and subsequent submission to the sponsoring agencies.

To date, the Computed Tomography Subcommittee report has been finalized, and its findings and recommendations have been submitted to the sponsoring agencies for consideration. In addition, the Cardiac Catheterization Laboratories Subcommittee submitted its study to the FHRSC in January 1979. However, the committee deferred final action on this report until its March 20 meeting.

Because of internal changes in the membership of the FHRSC, establishment of all the subcommittees and the completion of their assignments was deferred until fiscal year 1979.

The FHRSC is presently on schedule in its approach to its activities.

NATIONAL CENTER FOR HEALTH SERVICES RESEARCH

Question: Please detail by subject area the research projects supported by NCHSR.

Answer: NCHSR, through extensive discussion and formal conferences with components of the Department, State and local agencies, and other members of the health care sector, continues to refine and support a research agenda which identifies researchable issues in ten areas: Cost Containment; Emergency Medical Services and Ambulatory Care; Health Care and the Disadvantaged; Health Insurance; Health Manpower; Long-Term Care; Planning and Regulation; Quality of Care; Special Studies; and Technology and Computer Science Applications.

Question: How do those compare to research projects supported by the Health Care Financing Administration?

Answer: Health services research has been defined as the systematic and scientific investigation of problems in the organization, delivery, and financing of health care services. However, there is a major distinction between the research agenda of NCHSR and HCFA.

The mandate of NCHSR is broad; the legislation directs that its program of research, evaluation, and demonstration activities encompass virtually every aspect of health services research. NCHSR is responsible for ensuring that comprehensive and systematic efforts are made to develop new options for health services delivery and health policy, to test the assumptions on which current policies and delivery practices are based, and to develop the means for monitoring the performance of the health care system.

In contrast, the research objectives and priorities of HCFA are usually defined and constrained by the immediate information needs of its operating programs. The research and demonstration mission of HCFA is geared directly toward expanding our understanding of the Medicare, Medicaid, and Professional Standards Review Organizations (PSRO) programs so as to improve the operating effectiveness of these programs with respect to cost and quality of care. HCFA's program specific research emphasizes large-scale demonstrations, evaluations, and collection of program statistics and data related activities. The results of HCFA studies, experiments, demonstrations, and evaluations provide essential information used by decisionmakers in considering proposed policies and/or legislative changes which would affect the delivery of health care services to HCFA program beneficiaries.

There is considerable complementarity of interest between the general research agenda of NCHSR and the program related research agenda of HCFA. Consequently, through a formalized series of information and decision sharing meetings between senior staff of the two agencies, a combined research budget for NCHSR and HCFA during 1979-1980 has been prepared. This document which is submitted for the record provides a detailed description of the general and program specific areas of health services research supported by the two agencies.

(the information follows)

Joint Health Services Research Strategy and Budget, Fiscal Years 1979-80

Purpose

This document describes the agenda and strategy for health services research of the Health Care Financing Administration (HCFA) and the National Center for Health Services Research (NCHSR) for the fiscal years 1979 and 1980. Information is provided which highlights the extensive interaction between the two agencies for planning purposes, the complementarity between each organization's research efforts, and the specific priorities and estimated budget obligations for the areas of research supported.

HCFA/NCHSR Interaction

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Nonetheless, there is considerable complementarity of interest between the general research agenda of NCHSR and the program related research agenda of HCFA. Consequently, a number of procedures have been established to assure that the most effective research strategy for both organizations can evolve.

For over a year an informal group consisting of senior administrators for health services research in both HCFA and the Public Health Service (PHS) has met periodically to discuss general program dimensions and major research priorities. This group has been formalized more recently by agreement between the Assistant Secretary for Health and the Administrator, HCFA, to deal routinely with general matters of research policy. In addition, staff from both orgranizations are regularly included in the priority development activities that go on outside of their immediate organizational settings.

In order to assure project by project coordination, a number of more specific procedures have been implemented. Both HCFA and NCHSR routinely

exchange the fact sheets and abstracts of all grants which are transmitted at the same time that these grants are placed into the review process. This allows the early identification of multiple submissions from a single investigator to both agencies. It also provides each operating office with the opportunity to identify and direct interest in involvement in the research (e.g., the need for HCFA to obtain data to assess Medicare/Medicaid experiences). Representatives from HCFA have been invited to attend all NCHSR Study Section review activities and the staff of NCHSR have routinely participated in the grant review process at HCFA. Ample opportunity is provided for additional HCFA/NCHSR review and assessment throughout the entire process of grant review and funding decision. Finally, all contract research which is program dependent in any way is regularly discussed with HCFA prior to an NCHSR commitment to pursue the study.

These information and decision-sharing procedures, coupled with a significant difference in emphasis--for HCFA the program support focus is predominant while for NCHSR the general issues are more compelling--lead to a research agenda which reflects a high degree of complementarity and mutual productivity. Both HCFA and NCHSR will continue to invest in improving their capacity to identify under-supported research areas which can be strengthened by cooperative effort between the two agencies.

The section which follows describes the combined research budget for HCFA and NCHSR during FY 1979-1980, and provides a detailed description of the general and program specific areas of health services research supported by the two agencies.

Joint Budget and Areas of Health Services Research

The combined health services research budget of NCHSR and HCFA amounts to an estimated $51.7 million in FY 1979 and $69.6 million in FY 1980. The budget table immediately below arrays seventeen areas of research which comprise the general and program specific research mandates of NCHSR and HCFA, respectively. An increase of $17.9 million is indicated for total health services research supported by the two agencies during FY 1979-1980. This increase is primarily accounted for by new HCFA initiatives in issues dealing with long-term care, beneficiary impact, and integrated data systems. A description of each research area and related priorities follows the budget table.

(1) Beneficiary Impact and Related Activities - This program specific research area is designed to provide information on health care expenditures and utilization patterns of HCFA beneficiaries in order that HCFA programs may be more efficiently operated. Primary HCFA activities are: 1) to report and analyze the patterns and trends in health services utilization to determine if services are provided in as efficient and economical manner as possible; 2) to assess the use and cost of program benefits as well as the use of uncovered services; and 3) to determine the effectiveness of HCFA programs in removing barriers that prevent beneficiary access to health care services. During 1979-1980, HCFA projects will focus on developing information on beneficiary use of ambulatory services. This includes a major new survey entitled "Medical Care Utilization and Expenditure Survey" (MCUES) to provide national level data for the Medicare and Medicaid populations as well as non-Federal beneficiary data on covered and non-covered ambulatory care services. Additional HCFA projects will focus on the design and development of a Medicaid statistical system for reporting, research and program evaluation. Studies and information will be developed on previously unaddressed areas of importance including skilled nursing facilities (SNF) benefits, the end stage renal disease (ESRD) program, and the impact of HCFA pro-

NCHSR/HCFA JOINT BUDGET STATEMENT (FY 1979-1980)

Area of Research	NCHSR General Research ($000) 1979	NCHSR General Research ($000) 1980	HCFA Program-Specific Research ($000) 1979	HCFA Program-Specific Research ($000) 1980	Combined NCHSR and HCFA Budget ($000) 1979	Combined NCHSR and HCFA Budget ($000) 1980	Absolute Change (1979-1980)	Area of Research
(1) Beneficiary Impact	$ -	$ -	$ 3,100	$ 5,500	$ 3,100	$ 5,500	+ $ 2,400	(1)
(2) Cost Containment	3,148	2,720	7,000	6,000	10,148	8,720	- 1,428	(2)
(3) Emergency Medical Services and Ambulatory Care	1,713	1,624	-	-	1,713	1,624	- 89	(3)
(4) Fraud and Abuse	-	-	2,000	2,000	2,000	2,000	-	(4)
(5) Health Care and the Disadvantaged	201	577	-	-	201	577	+ 376	(5)
(6) Health Insurance	3,823	2,052	-	-	3,823	2,052	- 1,771	(6)
(7) Health Manpower	914	1,380	-	-	914	1,380	+ 466	(7)
(8) Health Systems Organization	-	-	4,000	4,000	4,000	4,000	-	(8)
(9) Industrial Organization and Reimbursement	-	-	500	500	500	500	-	(9)
(10) Integrated Data Systems	-	-	2,500	5,000	2,500	5,000	+ 2,500	(10)
(11) Long-Term Care	979	1,317	6,000	21,000	6,979	22,317	+ 15,338	(11)
(12) Physician Reimbursement	-	-	3,500	3,000	3,500	3,000	- 500	(12)
(13) Planning and Regulation	1,420	1,507	-	-	1,420	1,507	+ 87	(13)
(14) Program Evaluation	-	-	1,500	2,000	1,500	2,000	+ 500	(14)
(15) Quality of Care and Effectiveness	3,207	2,217	1,300	2,000	4,507	4,217	- 290	(15)
(16) Special Studies	1,459	1,195	-	-	1,459	1,195	- 264	(16)
(17) Technology and Computer Science Applications	3,440	4,011	-	-	3,440	4,011	+ 571	(17)
TOTAL	$20,304	$18,600	$31,400	$51,000	$51,704	$69,600	+ $17,896	

grams on the disabled. HCFA will continue to develop data for utilization review and health planning.

Estimated obligations: 1979, $3.1 million; 1980, $5.5 million

(2) Cost Containment - This research area entails analysis of the factors underlying the increase in health care costs and assessment of the means to modify these costs. Since cost containment involves making deliberate choices between competing uses of scarce resources, this issue includes most of the major problems of the current health care system. However, the general research focus of NCHSR is on the development and implementation of structural reforms of the system and the provision of incentives for more cost-effective utilization of health care resources. Selective priorities for research support in 1979-1980 include comparative analysis of the success and failure of market and regulatory-oriented cost containment strategies in this and other countries, with emphasis on the analysis of innovative cost-savings programs of management and labor. Support will also be provided for studies which examine the means to improve the economy and quality of drug prescribing. In response to a PHS initiative, analysis of the organization, delivery and impact of health promotion and prevention programs will be encouraged. Such analysis would examine the public and private means to affect change in lifestyle (dietary practices, stress management, smoking cessation) and the use of preventive services. Within HCFA, this program specific research area is designed to develop economic knowledge about hospital reimbursement behavior in order to respond to policy questions regarding changes in reimbursement systems and how these systems can improve the Federal and State third party payment programs. HCFA projects will support the efforts to develop and compare alternative reimbursement systems in anticipation of broader Federal authority for controlling inflation in hospital costs and demonstrate and evaluate the hospital cost containment potentials of alternative prospective payment and rate setting systems. Within this context, during 1979-1980 hospital economic behavior will be modeled, hospital outputs will be accurately measured, and improved hospital reimbursement and resource allocation systems will be designed. HCFA research projects will attempt to explain the variation in hospital cost levels and rates of hospital cost inflation, to measure hospital output differences with emphasis on case mix and case severity, to develop hospital and patient classification methodologies, and to test a variety of reimbursement systems. Ongoing NCHSR intramural analysis of the factors which affect service intensity in the hospital sector will provide additional detail for proposed HCFA investment in research on hospital costs and related price indexes.

Estimated obligations: 1979, $10.1 million; 1980, $8.7 million

(3) Emergency Medical Services and Ambulatory Care - This general research area encompasses analysis of the organization, utilization, production, resource requirements, and effectiveness of emergency medical and other ambulatory systems of health care. During 1979-1980, NCHSR will emphasize a continued synthesis and assessment of the operation and impact of emergency medical systems. Studies which analyze the ambulatory care resources necessary to meet the expected increased demand under various national health plans will be encouraged. In addition, NCHSR will continue to support studies on emergency medical techniques, methods, devices, and delivery, in its administration of the research program authorized by Section 1205 of the Emergency Medical Services Systems Act of 1973 and related amendments of 1976. (The budget shown for this document does not include Section 1205 funds.)

Estimated obligations: 1979, $1.7 million; 1980, $1.6 million

(4) Fraud and Abuse - This program specific research area is designed to implement section 17(d) of P.L. 95-142, which is "to develop and demonstrate improved methods for investigation and prosecution of fraud in the provision of care or service under the health programs established by the Social Security Act." During 1979-1980, HCFA will conduct projects which include innovative State methods to detect fraud and abuse in hospitals as well as long-term care facilities. Current Medicare and Medicaid procedures will also be examined in an effort to determine their applicability or adaptability as a fraud and abuse investigative tool.

Estimated obligations: 1979, $2.0 million; 1980, $2.0 million

(5) Health Care and the Disadvantaged - This general research area includes analysis of the need for and utilization of services, the supply and accessibility of services, and the effectiveness of various public programs that address the health care problems of disadvantaged population groups. A recently completed set of research studies sponsored by NCHSR addressed the impact of adverse economic conditions on the health care of the disadvantaged. During 1979-1980, NCHSR will emphasize the synthesis of the important results of these studies in order to provide policy insight as to the effect of inflation and unemployment on health insurance coverage, use of community hospitals, and access to health care services. It is anticipated that a selected research agenda keyed to the particular health care problems faced by Hispanic-Americans will evolve for consideration by various research components of the Department during 1980. Collaborative efforts within PHS and with HCFA will also generate selected studies on issues in child health care. Results of planned NCHSR activities in this area will complement the much larger set of program specific research studies to be undertaken by HCFA on beneficiary impact.

Estimated obligations: 1979, $201 thousand; 1980, $577 thousand

(6) Health Insurance - This general research area encompasses analysis of the socio-demographic, economic, and administrative implications of various health insurance initiatives. NCHSR has been directly involved in helping to build the analytical foundation for national health insurance. There are three major priorities for further investment in this research area by NCHSR. First, NCHSR has undertaken the National Health Care Expenditures Study. This intramural research program will examine the cost, utilization, and financing implications of various national health insurance proposals; the cost of illness for different diagnostic problems in different treatment settings; the distribution of benefits to individuals in business from current tax law on medical and health insurance expenses and the potential change in the distribution of benefits were such laws to change, among other important health insurance policy questions. The analyses will be based on the National Medical Care Expenditures Survey (NMCES) supported by NCHSR and implemented in collaboration with the National Center for Health Statistics (NCHS). This survey will provide detailed information for the year 1977 about the way health care services are used in this country and the pattern and character of health care expenditures involved. NMCES differs from the proposed Medical Care Utilization and Expenditure Survey (MCUES) to be conducted jointly by HCFA and NCHS in that NMCES is a cross-sectional picture of health expenditures for a given year while MCUES entails a continuing annual survey with greater emphasis on Medicare and Medicaid beneficiaries. Second, as mandated in P.L. 95-623, NCHSR is to evaluate

the impact of recent United Mine Workers health benefits and financing package on the provision and utilization of health care services by beneficiaries. This study, and required report to the Congress, will help to focus on the supply, demand, and outcome effects associated with the imposition of cost sharing. Finally, NCHSR will continue to address the important questions dealing with catastrophic or high cost illness. Research will be encouraged which helps to determine whether high cost treatments are based on a "unique" production process and how this process differs according to treatment setting.

Estimated obligations: 1979, $3.8 million; 1980, $2.1 million

(7) Health Manpower - This general research area involves analysis of the economic and behavioral aspects of health manpower education, requirements, distribution, utilization, and development. PHS is currently engaged in a reevaluation of its health manpower policies. Research is required that explores the factors and incentives which can lead to more efficient and equitable use and distribution of health manpower. Consequently, NCHSR research priorities for 1979-1980 include the analytical development of techniques and models to forecast various health manpower needs at the regional, State, and local level. Empirical analysis of the optimal mix of physician and non-physician health care providers including issues of manpower substitutability and task delegation will be supported. Current NCHSR technical support for the Graduate Medical Education National Advisory Committee (GMENAC) and interest in evaluating alternative financing options for graduate medical education will be continued. Studies in this area will complement HCFA's major program interest in the reimbursement and participation of physicians in Medicare and Medicaid.

Estimated obliations: 1979, $914 thousand; 1980, $1.4 million

(8) Health Systems Organization - This program specific research area is based on the consensus that the existing incentives in the health care delivery system induce certain inflationary and inefficient provider behavior and fail to provide all Federal beneficiaries with satisfactory access to health care services. This incentive system is dominated by fee-for-service reimbursement to physicians and cost reimbursement to institutions, both of which result in incentives for inefficiency. The intent of HCFA projects in this area is to seek organizational and payment methods which reduce costs by 1) accepting the essential features of the current health care delivery system but attempt to modify incentives by developing alternative reimbursement methods and 2) instituting fundamental changes in the organization of health care delivery. HCFA research efforts in this area during 1979-1980 are focused on a) alternative delivery system approaches such as Health Maintenance Organizations (HMO's), and providing incentives for Medicare and Medicaid beneficiaries to join such organizations as well as encourage HMO's to enroll Federal beneficiaries; b) the cost and quality impact of broadening Medicare and Medicaid coverage for ambulatory services and for new categories of providers such as free standing radiation centers; and c) evaluating the effectiveness of the end stage renal disease program and encouraging home dialysis.

Estimated obligations: 1979, $4.0 million, 1980, $4.0 million

(9) Industrial Organization and Reimbursement - This program specific research area will assess the effects of HCFA reimbursement policies on various industries in the health care sector including laboratories,

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durable medical equipment, dental care, drugs and medical supplies. The products of these industries constitute a significant share of the medical care bill of the nation. The purpose of HCFA research in this area will be to understand how HCFA reimbursement policies affect the market structure and market performance of each industry. During 1979-1980, HCFA studies will focus on the nature of the demand for each industry's output, measure the degree of market concentration and ascertain if barriers to competition exist. These research projects will also examine market conduct with respect to advertising and promotion of the product, research and development expenditures, and pricing policies and profits. The relationship of industry suppliers to other providers in the health care sector, particularly with respect to pricing and utilization decisions, will also be studied. HCFA will work closely with NCHSR on its research of the medical equipment/technology industry to minimize duplication of effort and to assure complementarity of research projects.

Estimated obligations: 1979, $0.5 million; 1980, $0.5 million

(10) Integrated Data Systems - This program specific research area encompasses the development, testing, demonstration, evaluation and implementation of uniform billing, discharge, cost, and utilization reporting systems as specified in Section 19 of P.L. 95-142, and their integration into a national health information network. This network will serve the administrative and research needs of HCFA's operating programs as well as provide the administrative basis for a national health insurance program. The focus of this effort is to replace the redundancy and overlap of the present mosaic of noncompatible local, State and national data systems with a national framework and protocol for uniform reporting of health care data. During 1979-1980, HCFA will implement a hospital cost reporting system for Medicare and Medicaid called the System for Hospital Uniform Reporting (SHUR). In addition, uniform cost reporting systems for long-term care facilities, home health agencies and health maintenance organizations will be developed and tested. HCFA will also conduct demonstration projects to test integrated data systems which include SHUR as well as uniform billing and discharge reporting. Additional HCFA projects will focus on alternative data entry methodologies, use of combined forms to improve data accuracy and consistency, optional data sets to meet unique State or area needs, and variations in organizational arrangements for processing data.

Estimated obligations: 1979, $2.5 million; 1980, $5.0 million

(11) Long-Term Care - Long-term care is defined as care for the chronically ill and the physically or mentally disabled and includes a wide variety of health, social and personal care services generally needed over an extended time period. Long-term care services can be rendered in institutional settings as well as in ambulatory and in-home settings. The increasing cost of long-term care and the increasing public demand for additional services has resulted in an HEW Department-wide initiative in this area. HCFA's main focus during 1979-1980 will be directed toward large-scale demonstrations of alternative approaches to the organization and delivery of coordinated systems of long-term care at the community level, expansion of program benefits such as hospices, and financing and reimbursement reforms such as a voucher payment system to Medicare and Medicaid beneficiaries for the purchase of services. In addition, HCFA research, evaluations and statistical studies will be conducted on the economics of the long-term care service industry, factors affecting utilization of various types of long-term care services,

quality and utilization control mechanisms such as PSRO longterm care reviews, and the system impact of major change in public funding for non-institutional services. During 1979-1980, NCHSR will emphasize research on issues dealing with the deinstitutionalization of long-term care services. In particular, analysis of the care and services provided to the chronic mentally ill who have transferred from mental hospitals to alternative care settings will be undertaken. This is responsive to the concerns and questions raised by the recent Deinstitutionalization Task Force and the Department's research agenda for multi-agency activity on long-term care issues. Syntheses of information derived from previous investment in research on long-term care issues will be encouraged.

Estimated obligations: 1979, $7.0 million; 1980, $22.3 million

(12) Physician Reimbursement - This program specific research area focuses on physician costs in the health care delivery system. The physician is the central decisionmaker in the system and thus physician reimbursement methods permeate virtually all aspects of the health care system. During 1979-1980, HCFA will emphasize four major project areas. The first area is descriptive and behavioral analyses. HCFA will conduct analyses of physician practice patterns, physician costs and prices, physician incomes, physician productivity, and factors affecting Medicare assignment and physician participation in the Medicaid program as well as private insurance programs. The second area is development of reimbursement controls. HCFA projects will include refinement of an economic index, analyses of the effects and implications of various fee schedules and fee schedule negotiating systems, development of a uniform procedure terminology system, and design of a relative value scale (RVS) system according to various methodologies as well as validation of existing RVS systems. The third HCFA project area comprises projections, simulations and actuarial analyses of historical data, physician supply, insurance prices, utilization expenditures and incomes, and alternative physician reimbursement methods. Finally, HCFA will conduct demonstration projects designed to test alternative reimbursement methods for physician services with special emphasis on increasing physician participation in the Medicare and Medicaid programs.

Estimated obligations: 1979, $3.5 million; 1980, $3.0 million

(13) Planning and Regulation - This general research area is concerned with the development of the concepts and methods which are crucial for making more cost-effective investment and production decisions in the health sector and the analysis of market- and regulatory-oriented strategies for shaping such decisions. As evidenced by its solicitation in 1978 entitled "Grants for Cost Containment Research for Health Planning," NCHSR is acutely aware of the concerns and problems of State and local entities on the front line of health planning. Consequently, NCHSR research priorities during 1979-1980 will include development of better techniques for projecting the demand for services, for forecasting health expenditures, and for reviewing projects and allocating resources. Studies which examine the factors and incentives that lead to cost-effective consolidation, mergers, and sharing of institutional services will be encouraged. Support will be provided for the development and evaluation of decision rules and models for allocating health care resources at various jurisdictional levels and between various programs. Priority will also be given to analysis of the potential economic, political, and health system impact of institutional conversion/closure options and criteria to be used in allocating hospital capital expenditure limits. In collaboration with the Office of Health

Regulation (HCFA), study of both the positive and negative consequences of regulations in the health sector and the cost-effectiveness of such interventions will be supported.

Estimated obligations: 1979, $1.4 million; 1980, $1.5 million

(14) Program Evaluation - This program specific research area is designed to determine the effect of HCFA programs on its target populations and to analyze program management to determine its effect on the attainment of HCFA's programmatic goals. Three activities are encompassed in this program area: first, to plan and coordinate all HCFA program evaluation activities; second, to conduct selected program evaluation projects, and, third, to be the principal point of contact with organizations inside and outside of HEW on program evaluation matters. During 1979-1980, HCFA will conduct three major evaluations. The first is the continuing evaluation of the Professional Standards Review Organization (PSRO) program. This project consists of numerous studies which include analysis of Medicare claims to determine the impact of PSRO's on utilization and potentially abused diagnoses; cost-benefit analysis of Medical Care Evaluation Studies (MCEs); analysis of the impact of PSROs on unnecessary surgery and quality of care, examination of expenditures on specific diagnoses focusing on variations in treatment settings and PSRO-induced changes in hospital expenditure patterns; analysis of program expenditures; and evaluation of alternative review programs. The second evaluation undertaken by HCFA will be to examine the Maximum Allowable Cost (MAC) program for drugs. This project will focus on the impact of the MAC program on total outpatient Medicaid reimbursements and the program's overall cost-effectiveness. Finally, HCFA will attempt to evaluate the Early Periodic Screening Diagnostic and Treatment (EPSDT) program for children. This project will focus on the characteristics which account for positive and negative program performance as well as evaluate the program's overall effectiveness.

Estimated obligations: 1979, $1.5 million; 1980, $2.0 million

(15) Quality of Care and Effectiveness - Health services research in this area addresses the relationship between the health services that are provided and the health of the population. For NCHSR, this general research area specifically involves analysis of the measurement of health status, the evaluation of system and organizational performance with respect to health outcome, the study of various malpractice issues, and the development and assessment of procedures for monitoring the process of care. For 1979-1980, a major NCHSR activity will be to synthesize information derived from prior investment in this research area. In addition, a comprehensive Patient Status Assessment tool developed by NCHSR for the Section 222 Day Care and Homemaker experiments will be used to measure the effect of the implementation of a coordinated system of utilization review and care planning on patient status in intermediate care facilities. For HCFA, this program area is concerned with the issues of developing standards of care for Federal beneficiaries. During 1979-1980, methods will be developed by which quality of care can be assessed. In addition, the application of these methods to different types of providers and health care settings will be explored. HCFA will also conduct studies concerning variations in medical practice and the capacity to influence or modify such practice. Professional Standards Review Organizations will be monitored and innovative ways of checking the quality and effectiveness of care within a PSRO area will be studied. Projects will include testing the feasibility of changes in case-mix severity on PSRO outcomes and the impact of Medical Care Evaluations (MCE) on changing medical care practice. HCFA will also support the development of cost-benefit analyses to evaluate the effectiveness of second opinions in elective surgery, the

variation in rates of surgery in different regions and the resulting effect on beneficiary health status.

Estimated obligations: 1979, $4.5 million; 1980, $4.2 million

(16) Special Studies - NCHSR occasionally supports potentially important research activities that do not relate directly to its most immediate research emphases. Often designed to meet a special Departmental request, ongoing projects are concerned with exploring policy issues of emerging importance, with modeling broad areas of the health care system, with research methodology, or with facilitating the application of useful new research findings and products. One example of a special study is a collaborative effort between the Administration on Aging (AOA) and NCHSR to determine the extent health services delivery and financing may change because of the various State tax limitation programs prompted by California's Proposition 13. As an amendment to an AOA study of the effects of decentralized planning and administration of social and program funds, data are to be collected and analyzed in a field survey of eight states on the distribution of services and benefit to those age 60 and over. Another project, funded by the Communicable Disease Center (CDC) and NCHSR, will estimate the costs of selected medical events known or suspected to be related to the administration of specific vaccines. This analysis will aid in the planning of a program that provides for the compensation of persons who hold the government liable for adverse reactions following immunization. The results of this study will also serve as a measure of the benefits from prevention of the specified diseases which are the targets of vaccination.

Estimated obligations: 1979, $1.5 million; 1980, $1.2 million

(17) Technology and Computer Science Applications - This general research area encompasses analysis of technology-based approaches to modify the organization and delivery of health care services with special emphasis on the uses of computer science and medical information systems. NCHSR is committed to the continued undertaking and support of research which involves the design, development, demonstration, and evaluation of new technologies directly relevant to service delivery and organization. NCHSR will work closely with the new National Center for Health Care Technology (NCHCT) to minimize duplication of effort. In addition to its efforts on selected technology issues and its current technical assistance to NCHCT in the development of its own research agenda, NCHSR will continue to conduct and support research with respect to the uses of computer science in health services delivery and medical information systems. Specifically, analysis of the explicit benefits that can be realized from the use of various computerized information handling systems in both ambulatory and inpatient settings will be encouraged. Studies which assess the accumulated experience in the implementation of computerized medical information systems (including the social, political, organizational, and economic consequences of computerization) will be supported. The use of data systems that support effective medical decisionmaking by means of clinical data banks, statistical models, consultation programs, and other computer-based approaches will be emphasized. Other important research priorities during 1979-1980 include analysis of the impact of various governmental policies on the R/D and marketing strategies of the medical equipment/technology industry and the development of a systematic approach for selecting particular health care technologies for intensive evaluation.

Estimated obligations: 1979, $3.4 million; 1980, $4.0 million

Question: How are the research activities of NCHSR coordinated with HCFA and other agencies?

Answer: There is considerable complementarity of interest between the general research agency of NCHSR and the program related research agency of other PHS components and HCFA. Continuing discussion among senior officials of PHS will help to further mature ongoing cooperation. A number of information and decision-sharing procedures have, for example, already been established to assure that the most effective research strategy for both NCHSR and HCFA can evolve.

For over a year a formal group consisting of senior administrators for health services research in both HCFA and the Public Health Service (PHS) has met periodically to discuss general program dimensions and major research priorities. This group has been formalized more recently by agreement between the Assistant Secretary for Health and the Administrator, HCFA, to deal routinely with general matters of research policy. In addition, staff from both organizations are regularly included in the priority development activities that go on outside of their immediate organizational settings.

In order to assure project by project coordination, a number of more specific procedures have been implemented. Both HCFA and NCHSR routinely exchange the face sheets and abstracts of all grants which are transmitted at the same time that these grants are placed into the review process. This allows the early identification of multiple submissions from a single investigator to both agencies. It also provides each operating office with the opportunity to identify any direct interest in involvement in the research (e.g., the need for HCFA to obtain data to assess Medicare/Medicaid experience). Representatives from HCFA have been invited to attend all NCHSR Study Section review activities and the staff of NCHSR have routinely participated in the grant review process at HCFA. Ample opportunity is provided for additional HCFA/NCHSR review and assessment throughout the entire process of grant review and funding decision. Finally, all contract research which is program dependent in any way is regularly discussed with HCFA prior to an NCHSR commitment to pursue the study.

One very recent example of the interactive process is evidenced in a commitment to the development of cost containment research for health planning. Interagency discussions by NCHSR and BHPRD (currently the Bureau of Health Planning in HRA) led to a jointly sponsored conference (September, 1977) to address the development of cost containment strategies. A nationally representative set of State and local health planning agency officials were involved in both the design and the operation of the conference.

As a result of this interaction with both users of research findings and another component of PHS, the Director, NCHSR, was able to approve 24 projects for funding during FY 1978. In addition to $100 thousand of BHPRD support, NCHSR provided approximately $1 million for support of these approved projects. The research

activities in this area are not only relevant to the planning arena, but are germane to the emphasis on cost containment strategies found in both the PHS strategy and the recent request for specified research activities by the Undersecretary.

In other areas identified by the Department as appropriate for multi-agency research agendas NCHSR has taken the lead in developing new initiatives with other PHS components. For example, NCHSR is currently discussing the potential for a joint research solicitation with ADAMHA on mental health care issues; proposed NCHSR research on the deinstitutionalization of the mentally disabled is being strenghtened by professional interaction with program staff of ADAMHA. Significant research issues entailed in the allocation of a hospital conversion/closure program, and the monitoring of possible default on Federally subsidized loans in the hospital sector, are being addressed by NCHSR in cooperation with BHP and BHFFCC. Both NCHSR and NCHS collaborated on the Medical Care Expenditure Survey and are working together to achieve a better understanding of the methods required to quantify the costs of illness. NCHSR is also developing a computerized system which will allow rapid retrieval of data on all health services research projects. This will, in turn, provide a strong basis for a more efficient exchange of project information between agencies.

Question: Who is directly responsible for coordinating these various activities?

Answer: The Director of the National Center for Health Services Research has been given the responsibility by the Assistant Secretary for Health for coordinating research activities within the Public Health Service. The Deputy Assistant Secretary for Health Research, Statistics, and Technology and the Associate Administrator of HCFA are responsible for coordination between PHS and HCFA. No one has been given coordinating responsibility for all of the Department's activities as the authority rests with the Secretary. However, the informal coordinating procedures established between HCFA and PHS covers the health services research activities of the Department.

Question: How many research projects have been supported by NCHSR in the past five years?

Answer: The NCHSR has awarded 379 new health services research projects over the past five years.

Question: Please cite instances where the results of research projects supported by NCHSR have led to specific legislative or program initiatives.

Answer: There is rapidly accumulating evidence that NCHSR supported research has directly influenced recent health legislation, policy and working documents, Departmental programs, and health care systems and consumers. Selected examples are as follows:

- The report on the "Policy Implications of Medical Information Systems," prepared by the Office of Technology

Assment and published November 1977, is based entirely on projects initiated and funded by NCHSR.

- A report entitled, "Catastrophic Health Insurance," published by the Congressional Budget Office in 1977, is based largely on information provided by a series of studies funded through contract by NCHSR.

- NCHSR supported research on hospital cost functions was used as an empirical basis for the volume adjustment/ revenue limits of Phase IV of the Economic Stabilization Program and Phase I of the recently proposed Hospital Cost Containment legislation.

- NCHSR sponsored the development of a medical information system currently being employed by the Harvard Community Health Plan to provide most of the information required for patient care, patient management, and administrative support.

- Recent amendments to the Social Security Act, P.L. 95-210, the Rural Health Clinic Services Act, permit payment of physician assistants or nurse practitioners when services are rendered by such individuals. NCHSR, through its early support of the Primex, Medex, and various other physician extender research and demonstration programs, has been directly responsible for the acceptance of these physician substitutes. A substantial number of the articles used in the report, "Issues in Physician Extender Reimbursement," prepared by the Congressional Research Service and used by the Committees which initiated this bill, were funded by NCHSR.

- NCHSR is currently supporting twenty-four projects dealing with cost containment issues for health planning. The development of this research agenda involved major participation of State and local health planning representatives.

- The National Medical Care Expenditures Survey (NMCES), jointly supported by NCHSR and NCHS, will provide the first detailed information about the health care experience of the American people for the entire year 1977. Analytic studies within NCHSR will focus on the way health care services are used in this country and the pattern and character of health expenditures.

- According to an NCHSR supported analysis, a large segment of the unemployed work force is without any form of health insurance coverage and many are ineligible to apply for Federally-funded health care assistance. A related study, also funded by NCHSR, showed that between fifty and sixty percent of workers studied who became unemployed lost their health insurance coverage for an average of approximately twenty-two weeks.

Two NCHSR studies on the use of preventive services have shown that low-income women who have children use fewer preventive health services than those without children, and that the availability to a patient of a regular source of medical care encourages the use of preventive health services among the low-income urban population.

SCHOOL HEALTH EDUCATION

Question: You can't believe how many conflicting stories we get about what is and isn't being done in the area of school health education. As you know, the Committee directed your office to get in touch with the Office of Education and begin to initiate a new school health program. We received a report on this and now we are told by several people that only your office dealt with it and the Office of Education didn't even have any input into it. Would you like to comment on this? For the record, please give us five examples as specific as can be, as to what type of programs are presently in use in the schools because of this new coordination between your office and the Office of Education.

Answer: The Office of Education (OE) not only knew about the report but, in fact, helped write it; specifically, Dr. Helen Nowlis, Mr. Sy McNeely and Mr. Stan Krueger all participated in drafting this report. Dr. Nowlis is the Special Assistant for Comprehensive School Health to the Deputy Commissioner for Bureau of Elementary and Secondary Education.

Although there are no examples as yet of programs used in the schools, there are noteworthy cooperative activities in school health within the Department. These include:

- The OE is currently establishing an Office of Comprehensive School Health at the Deputy Commissioner level. (This office will report to a newly established Deputy Commissioner.)

- Two million dollars have been requested in the President's fiscal year 1980 budget proposal to implement P.L. 95-561, Education Amendments of 1978 which provide grants to State and Local Education Agencies for health education for operation of that office.

- The development of the regulations to be used by the office has been a cooperative effort by the OE, the Bureau of Health Education (BHE), and the Office of Health Information and Health Promotion (OHIHP) in my office.

- The Public Health Service is currently developing plans for a comprehensive evaluation to identify and evaluate promising school health activities. The development of this plan has been directed by the OHIHP and BHE, in consultation with OE.

- In addition to school health education, efforts are being made to expand school health services and one component of the Public Health Service's Child Health Initiative is the development of a School Nurse Practitioner Demonstration Program. It is anticipated that in FY 1980 this demonstration program will include twenty-five pilot projects.

NATIONAL CENTER FOR HEALTH SERVICES RESEARCH

Question: How many health services research centers are you supporting?

Answer: The National Center for Health Services Research currently supports seven research centers. The budget period of an eighth center expired on March 1, 1979 after a review of its activities indicated that continued institutional support would not be an efficient use of funds. That center was located at the University of Michigan.

Question: What kind of direction is given by the National Center to the types of projects undertaken and conducted by these centers?

Answer: The centers independently select, design, and derive budgets for the research projects they undertake. This degree of independence was clearly intended by Congress when the NCHSR's authorizing legislation was enacted. The NCHSR provides general direction in part through a formal annual review. That review reveals how a center seeks out and responds to research needs and opportunities to offer assistance and encourages the centers to undertake projects that are diverse and are useful to local and national concerns.

Question: Who disseminates the research produced by the Centers?

Answer: The centers are obligated to disseminate their products, and the adequacy of that effort is assessed during the annual review. The centers all publish and distribute periodic bulletins or newsletters, conduct seminars and presentations to broad audiences, and publish staff findings in professional literature and the popular press. In practice, the NCHSR contributes to their dissemination efforts. Their research reports, if supported directly through NCHSR, are distributed through the National Technical Information Service. Their staffs have contributed directly to NCHSR publications, and staff from the centers assist at NCHSR-sponsored "dissemination workshops." The latter are a series of local workshops for audiences consisting mainly of health planners and state and local government officials, and their objective is to bring the users of research in contact with recent findings and research methods.

Question: What other sources of funding support these Centers?

Answer: Only the three national "special emphasis" centers receive as part of their grant awards an amount to support research projects. The remaining four general research centers are required to seek outside funds. In practice all of the centers have obtained project support from other sources. They are foundation grant awards, contractual awards for their major technical assistance efforts with state and local governments, and grant and contract awards from Federal agencies for research projects.

HEALTH INFORMATION AND HEALTH PROMOTION

Question: The Congress in 1976 enacted legislation, P.L. 94-317, to support Health Information and Health Promotion activities in three areas: general authority, research and community programs. What exactly have you done in these three areas? What kinds of projects have you funded? What were they designed to accomplish? Did they accomplish anything? What do you see for the future of this program?

Answer: Since P.L. 94-317 was passed in June 1976, much of the activity authorized has been carried out by the Office of Health Information and Health Promotion (OHIHP). If we group the activities under the three areas of general authority, research and community programs, the following points can be identified.

General Authority. The general authority used by the OHIHP is in exercising its role as coordinator of health information and health promotion activities within the Department. Coordinative activities undertaken by the OHIHP include several program activities, as well as Departmental task forces chaired by the Acting Director for the Office of Health Information and Health Promotion.

The OHIHP staff contributed to and provided support for the Departmental Task Force on Prevention, the Task Force on Smoking and Health, and the Task Force on Sexually Transmissible Diseases.

The OHIHP staff serve as principal staff support for the operation of the Department's Nutrition Coordinating Committee. Four major issues being addressed by the committee are: nutrition education, implementation of a nutritional status monitoring system, review of national dietary guidelines, and international nutrition activities.

To develop a comprehensive and coordinated school health program, the OHIHP continues to work with the Office of Education (OE) and the Bureau of Health Education, Center for Disease Control, in their efforts to develop school health curricula and strengthen school health education programs and health services delivered in the schools.

OHIHP staff is working with the Federal Trade Commission and the Federal Communications Commission to develop proposed rulemaking relative to food advertising directed at children.

In addition to other coordinative activities, regulations are currently being prepared in order to develop programs of grants to be awarded under Title XVII of the Public Health Service Act. The office will develop the overall policy direction for these regulation documents and coordinate the programs of grants operated by various Public Health Service (PHS) organizational components. Completion of the Department's Task Force Report on Prevention provided a substantive review of current Departmental prevention activities. This information was used to identify areas of unmet needs and strategies to address those needs as part of the Prevention Initiative.

Some specific cross-cutting activities being done by OHIHP include:

- Preparing the Surgeon General's Report on Prevention
- Advising on the prevention component of the National Health Plan
- Cost/benefit analyses of existing disease prevention and health promotion programs
- Implementation and operation of a National Clearinghouse on Health Information
- Coordination of a National Nutrition Education Conference in September 1979

The office also published Health Highlights, a small booklet designed to inform the general public about trends affecting health.

As part of OHIHP's health information activities, a display was developed for the Department's 25th Anniversary Celebration to provide information to the general public about activities which they can employ to improve their own health.

Contracts awarded under these general authorities in FY 1978 and continued in FY 1979 included the development of resource documents by the Institute of Medicine for preparing the Surgeon General's Report on Prevention and the conduct of a feasibility study to develop options for the specific functions of a National Health Information Clearinghouse. The results of these contracts have been to give valuable state-of-the-art information in completing the Surgeon General's Report as well as provide a good basis for the implementation and operation of the Clearinghouse to be funded in FY 1979.

Research. Because the activity of OHIHP is principally a coordinative one, a major research activity was the identification of research priorities during the development of the Department's Task Force Report on Prevention. Further, as the preliminary phase of the study of Insurance Coverage of Preventive Services, mandated by Section 1705(b) of the PHS Act, the OHIHP is identifying existing research on coverage of health education and preventive health services by private insurers, Blue Cross plans and Medicare and Medicaid.

The office has also funded a project in collaboration with the National Center for Health Statistics which is a two-phased national survey of the American adult population to determine the relationship between health habits and health status. Preliminary results of this study will be available in November 1979.

Community. In addressing activities for the community, the OHIHP is developing a National Health Promotion Program. It is a coordinated series of activities designed to facilitate individual understanding of certain personal habits in improving health. This program will strengthen the Administration's efforts to provide health information and education in a variety of settings: school,

worksite, community, medical treatment, and home (including television and radio). The target emphasis of the program will be: prudent diet, smoking reduction, hypertension control and physical exercise. Activities under the program include: eight regional forums on community health promotion to be conducted from February through October 1979; a recently conducted Conference on Health Promotion in the Occupational Setting; other conferences planned for this year on nutrition education and lifetime exercise; and a national health promotion media campaign to develop certain media spots and pertinent printed materials.

Much of the above activity was funded in late FY 1978 and is continuing in FY 1979. One regional forum has taken place in San Diego, California. Although preliminary indications were positive because of good speakers, much was learned in terms of the need to have greater participation of community leaders including elected officials.

The Conference on Health Promotion in the Occupational Setting was very successful in drawing participants from business, industry and labor unions. State-of-the-art papers enhanced the sharing of knowledge for the participants. Requests for the proceedings of the Conference are in great demand, numbering literally in the thousands.

Efforts are currently under way in providing technical assistance to 18 communities which are developing, implementing, or substantially expanding programs emphasizing reduction of health risks to individuals through changes in personal habits they may be motivated to make. Results of these efforts will be available by early next calendar year.

Other office activities include plans for a National Health Fair Program whose goal is to provide the foundation for a self-perpetuating nationwide "Health Fair Week" each year; sponsoring a model health fair in the Summer of 1979; and joining with NBC, Red Cross, Blue Cross, and the National Health Screening Council to promote a "National Health Fair Week," April 2-6, 1979.

Along with these areas funded in FY 1979 is development of a media campaign to increase the level of public awareness of health practices and to improve the health status of the American people, including: public service announcements; stimulation of public service programming; strengthening communication with media physicians and broadcasting executives; and exploration of potential applications of cable TV and satellite telecommunications for disseminating health information to the public.

Future Activities

Future activities of the Office of Health Information and Health Promotion will include, as budget allows, expanded efforts to provide assistance to communities for development of health promotion programs; stimulate the development of wellness programs in the HMO setting; expand studies into the costs and benefits of prevention activities; expand the use of media as a source of health information; facilitate the development and evaluation of health risk appraisal as a risk reduction technique; further assist the Office of Education

and the Bureau of Health Education in the development and evaluation of school health education curricula; and continue to coordinate health information and health promotion activities within the Department and among governmental and non-governmental groups. Activities conducted by the Bureau of Health Education and the Office on Smoking and Health to achieve the goals of the campaign against smoking will also be carried out under Title XVII authority during fiscal year 1979.

GRANTS TO STATES

Question: You are proposing that the Grants to States program will be reduced from $90 million to $52 million, while at the same time providing an offset of $18 million for formula grants at the Center for Disease Control and Preventive Medicine. This $18 million obviously does not make up the difference between $52 and $90 million. With that in mind, Dr., how do you expect the States to pick up this amount?

Answer: Under the provisions of the Health Services and Centers Amendments of 1978, P.L. 95-626, formula grants under Section 314(d), formerly known as Comprehensive health grants to States, will be known as Health Incentive Grants beginning in fiscal year 1980. These grants will be awarded to States according to a formula based on State population, a State's financial need and the proportion of State and local expenditures for comprehensive health services as a percentage of the National totals.

Over the years increased Federal resources have been made available through other authorities to support specific programs which address many of these same public health needs. Latest available data show that 314(d) funds allocated to State health agencies constituted only about 2 percent of the reported expenditures of the States for health services.

Though funding for the 314(d) program is being reduced in 1980, this decrease will be more than offset by increased support provided under other programs in the 1980 budget request. For example, there is $18 million of new funding in 1980 requested under the new Prevention Formula Grant and the $99 million requested for the ADAMHA Consolidated Formula Grant includes support for mental health activities formerly supported by the 314(d) program. In fact, total funds available to States, local governments and related health agencies in the 1980 request will provide a net increase of $43.5 million over 1979 funding levels.

OFFICE OF HEALTH PRACTICES ASSESSMENT

Question: The HEW-Labor FY 79 Conference Report provided for the phasing out of the Office of Health Practices Assessment.

What actions have you taken with regard to transfering responsibilities and personnel assigned to that office?

Answer: The Office of Health Practices Assessment has been phased out and the functions transferred to other appropriate offices. The personnel have found other employment on their own or through internal placement programs.

HMOs

Question: On the average, how much federal financial assistance is awarded to an HMO during the process of qualification?

Answer: No funds are awarded specifically during the "process of qualification." We do provide funds to developing HMOs who eventually seek qualification. We fund feasibility grants up to $75,000, planning grants up to $200,000 and initial development (ID) grants up to a maximum of $1 million (in FY80 this amount increases to $2 million). However, many grantees do not necessarily utilize the maximum amount allowable, particularly in the ID phase. On the average, grantees have received approximately $1 million total during their developmental stages.

Question: How long does the process of qualification generally take?

Answer: A determination is made within 120 days unless the applicant requests a longer time. A year ago there were 24 active applications of which 20 were over 120 days old. Today there are 16 applications pending. Of these, 9 are in active review (none are over 120 days old) and 7 are in suspense because the applicant has requested additional time or the application is incomplete.

Question: What kind of monitoring activities are conducted to evaluate the performance of an HMO?

Answer: The Office of Health Maintenance Organizations initiated a newly organized compliance monitoring process to evaluate the performance of HMOs. Operational data on HMOs is routinely collected through the National Data Reporting Requirements describing the financial condition of the HMO, the current membership level, and the service utilization levels experienced by members. The early warning system is designed to screen this data to identify those HMOs experiencing marketing, utilization, and/or financial trends which may be indicative of noncompliance with requirements of the Act. These HMOs are then subject to in-depth analysis by the compliance officers, assisted by a staff of specialists, to determine the need for further compliance action, such as formal evaluation or notice of noncompliance. As a result of this analysis, HMOs may be found to have weaknesses in their operation but still be maintaining legal compliance with the Act. These HMOs then would be referred to the Division of Development and regional offices for technical assistance.

Question: How many people do you now have working in compliance activities?

Last March, Mr. Champion indicated that 24 persons would be working in measuring HMOs, against a set of key variables for success or future on-site visits, and enforcement of the dual choice provisions of law.

Answer: The Division of Compliance now employs 32 full-time permanent employees, two HEW fellows and an IPA fellow.

HEALTH REGULATIONS

Question: The Committee has learned that the regulations for the Nurse Training Act of 1975 were finally published -- but only 5 days before the law expired. At this point in time, Dr. Richmond, how many regulations are presently pending right now within your health programs that have yet to be published and implemented?

Answer: There are currently in various stages of completion 85 separate PHS regulations. This varies from the initial draft to some which are in the last stages of review and almost ready for publication in the Federal Register. Within the Office of the Assistant Secretary for Health regulations are pending for adolescent health, health technology and physical fitness and sports.

SURGEON GENERAL'S REPORT ON PREVENTION

Question: When do you expect to release the Surgeon General's Report on Prevention? Could you share with the Committee any interesting findings or recommendations of this report in advance of its release? How much money will this report cost to prepare through its completion?

Answer: The Surgeon General's Report on Prevention will be released within the next month. It is not intended to be a detailed Federal plan with specific recommendations for Federal action in prevention, but rather will be a report to the American public which suggests priority areas for action within the control of individuals and communities to promote health and prevent disease. It is as such intended not to be a work plan, but to enhance individual and national perspective on the opportunities for better health. The report establishes goals for health improvement for each of the five major life stages (infants, children, adolescents, adults and older adults) and identifies key activities in three general areas: health promotion, health protection, and preventive services.

The report will cost approximately $200,000 to prepare through its completion. About $165,000 of that amount was used to purchase the services of the National Academy of Sciences, Institute of Medicine, to complete resource documents for the state-of-the-art in various areas included in the report. Other costs were for reproducing copies of several different drafts and staff time in drafting, reviewing, and redrafting parts of the report. Because review of the drafts of the report included persons at the White House and other Executive Branch agencies, it is difficult to assess the exact costs.

NATIONAL CENTER FOR HEALTH CARE TECHNOLOGY

You are proposing a reprogramming of over $3 million to initiate the new National Center for Health Care Technology.

Question: Why do you think this program cannot wait to be funded until fiscal year 1980?

Answer: The Department of Health, Education, and Welfare is implementing P.L. 95-623 as rapidly as possible, beginning with a request for reprogramming of FY 1979 funds, for a number of reasons:

1. The deep interest shown by a number of members of Congress in both Houses, and the sense of urgency they attached to the speedy implementation of the law;

2. The NCHCT is the agency of HEW charged with providing recommendations to HCFA on Medicare coverage of specific medical technologies. This is an extremely important function, with a constantly high volume of issues which need analysis. At the present time, 50 coverage issues are pending;

3. P.L. 95-623 requires that in addition to the consideration of safety and effectiveness, HEW studies of technology should encompass cost-effectiveness issues, and social, ethical, and economic implications as well. The former issues are addressed by the Food and Drug Administration, Center for Disease Control, Alcohol, Drug Abuse, and Mental Health Administration, and National Institutes of Health in their reviews of drugs, medical devices, and surgical procedures. However, there is no other HEW agency equipped to conduct analyses in the latter areas or to coordinate the results of both sets of analyses;

4. P.L. 95-623 required that the initial appointments to the National Council of Health Care Technology be made by the Secretary within 120 days of enactment. A list of candidates has been submitted to the Secretary for approval. It is expected that the Council will begin meetings in late spring.

Question: Why have you decided that you want to take another $3 million away from NIH in order to start this program?

Answer: The decision to reprogram funds from NIH was based on the level of technology-related research activity currently supported by the various institutes and the relative benefit that will be received from the studies to be performed. The technologies will be evaluated and the results will be applicable to the broad range of research efforts at NIH.

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Question: For the record, I would like to know for each institute, what programs would be cut in order to allow this reprogramming request?

Answer: In fiscal year 1979, a staffing and program level of 21 positions and $3.5 million is required to initiate and implement this much needed activity. A number of actions are required to establish the Center. First, we are requesting your approval to reprogram one position from the OASH Program Direction and Support Services activity and 14 positions and $350,000 from the National Center for Health Services Research (NCHSR) to NCHCT. Secondly, approval is requested to utilize 6 positions and $3,150,000 appropriated to the National Institutes of Health (NIH) for NCHCT activities.

The following distribution represents the level of resources in various NIH appropriations and OASH that will be used for health technology contracts and staffing costs.

NIH	Positions	Amount
National Cancer Institute	4	$1,330,000
National Heart, Lung and Blood Institute	2	560,000
National Institute of Dental Research		105,000
National Institute of Arthritis, Metabolism and Digestive Diseases		210,000
National Institute of Neurological and Communicative Disorders and Stroke		105,000
National Institute of Allergy and Infectious Diseases		140,000
National Institute of General Medical Sciences		70,000
National Institute of Child Health and Human Development		105,000
National Eye Institute		70,000
National Institute of Environmental Health Sciences		105,000
National Institute on Aging		70,000
Division of Research Resources		70,000
National Library of Medicine		210,000
Subtotal	6	$3,150,000
OASH		
National Center for Health Service Research	14	350,000
Program Direction and Support Services	1	---
TOTAL	21	$3,500,000

NATIONAL COOPERATIVE HEALTH STATISTICS

Question: a) Describe the status and various phases of CHSS.

b) What developments do you plan for the System in FY 1980?

c) How much more funding is required to make its various components fully operational?

Answer: a) The CHSS program currently has projects operating in 44 of the 50 States, Guam and Puerto Rico.

For fiscal year 1980, the budget for the Cooperative Health Statistics System will permit the completion of the vital statistics and health manpower components in all 50 States, the District of Columbia, and Puerto Rico. Depending on the Department's decision on the facility component, there may be some readjustment among the three components. The following table shows the number of projects by component:

National Center for Health Statistics
Cooperative Health Statistics System - Implemented Components and Costs (Dollars in Thousands)

	FY 1978		FY 1979		FY 1980	
Vital Statistics	44	3,820	44	3,820	53	5,680
Health Manpower	36	2,845	36	2,843	52	4,780
Hospital Care	9	1,261	8	800	a/	0
Ambulatory Care	1	67	1	70	1	100
Long-Term Care	1	67	1	70	1	100
Health Facilities	36	2,385	36	1,800	36	1,800
State Agency Development	0	0	4	400	10	1,000
Totals	127	10,443	130	9,803	153	13,460

a/HCFA will have lead responsibility for implementation of the Uniform Hospital Discharge Data Set (UHDDS).

b) Vital statistics and the health manpower component activities will be completed in all States by the end of fiscal year 1980. The completion of the health facilities component is dependent on cooperative arrangements with HCFA's developing System for Hospital Uniform Reporting (SHUR). The rate of implementation of the hospital statistics component by HCFA will depend, in large part, on the level of future appropriations, as well as the resolution of technical problems inherent in the development of a newly designed system.

The enabling legislation for the NCHS provides for a designated State agency to assume administrative responsibility for the health statistics activities at the State and local level. Guidelines are to be provided by the Department as to the functions of these agencies in assuring appropriate quality, completeness, and access to health statistics collected under the CHSS. At the same time,

the HCFA, in response to Public Law 95-142, the Medicaid-Medicare Fraud and Abuse Act, will designate State and/or regional processors to collect and process health facility and hospital utilization data. These processors will provide data tapes to the State designated CHSS agencies which will be responsible for quality control, data dissemination, maintenance of confidentiality, interface with State and local users, and the provision of sample or complete data tapes to agencies at the national level through NCHS. The estimated date for completion of these State level activities are difficult to forcast.

c. Current estimates to fund the designated State agencies are that a minimum of an average of $250,000 per State -- a total of $12,500,000 nationally -- is required to permit them to function to coordinate health statistics systems at the local-State level to meet the needs of planning agencies, State health and Medicaid agencies, Professional Standards Review Organizations, rate review and rate setting agencies, third-party payers, and so forth. A substantial share of direct funding for the operational costs may be provided through local-State users, State legislatures, and other State level agencies. However, the estimated $250,000 provided by PHS per State would permit improved access to data on a more timely basis and would assure the development of extensive cost efficiencies in data collection and analysis. These agencies would have functional responsibilities (1) to assure appropriate access to health data; (2) to protect privacy and confidentiality of data where required; (3) to assure the quality, uniformity, and relevance of data for priority needs for information; and (4) to operate under all available voluntary and mandatory reporting requirements of the State and Federal Governments to assure compliance.

An approximation of funds to be provided through the PHS, therefore, to assure that the components are fully developed and operational to meet all needs for data (local-State-national) is $30,000,000. This includes the funding described earlier for the support of the State designated Centers, and the vital statistics, health manpower, and health facilities components and assumes funding for the facilities utilization components will be provided through HCFA and/or data consortia at the State and local levels. Also included in the estimate is the Federal support for the provision of technical assistance, training, and limited research and demonstration activities.

PHYSICAL FITNESS AND SPORTS

Question: What explanation can you give for the decrease requested in 1980 for your physical fitness and sports program?

Answer: Congress last year mandated in P.L. 95-626 that in the interest of efficiency the work of the President's Council on Physical Fitness and Sports should be aligned with the work of the Office of Health Information and Health Promotion in a newly formed Office of Health Information, Health Promotion, and Physical Fitness and Sports Medicine. The current Public Health Service organizational alignment meets that Congressional mandate, and it is anticipated that closer coordination of program activity will result in reduction of duplication, and therefore will require less resources.

Specifically, Congress appropriated an additional $200,000 for expanding public information campaigns and new projects in the areas of cardiovascular diseases and obestity. These efforts will all be undertaken as part of the National Health Promotion program which will emphasize informing the public about measures to be taken in four key areas: exercise, nutrition, smoking, and hypertension control. The immediate activities of this program and the information dissemination function of the National Health Information Clearinghouse should reduce the needs for additional monies for the operation of the Council's information functions.

Finally, part of the additional monies will be used during fiscal year 1979 to operate a National Conference on Physical Fitness and Sports for All, also mandated in P.L. 95-626. This will be a one-time only conference and additional funds for it consequently will not be required in fiscal year 1980.

PHS HOSPITALS

Question: Can you guarantee us that there will be no reductions in patient care in fiscal year 1979 or 1980 and that all the positions which were allowed last year will be allowed to be filled?

Answer: No, I cannot make that guarantee. However, I can say that, based on present plans for fiscal year 1979, we have no reason to anticipate a reduction of patient care below the 1978 level. On the other hand, the fiscal year 1980 budget request calls for a slight reduction below the 1979 level in patient care provided by the PHS hospitals, to be partially offset by an increase in contract medical care services. Moreover, based on the congressional reduction of positions for the PHS hospitals and clinics from the 1978 level, 75 positions allowed in fiscal year 1978 will not be allowed to be filled in 1979 and 1980.

Question: As you know, Secretary Califano last year commissioned a complete study of the Public Health Service hospitals. Explain to this Committee how you expect the recommendations of this report to be carried out with your budget request an both fiscal years 1979 and 1980.

Answer: Upon receipt and review of the report by the Ad Hoc Advisory Committee, the Secretary directed that a study be made comparing private sector costs to those of the PHS Hospital and Clinic system for providing health care and that an implementation study be conducted to determine the actual steps needed to be taken by the system to fulfill the Ad Hoc Advisory Committee's recommendations. Since neither the cost comparison study nor the implementation study has been completed, the fiscal years 1979 and 1980 budgets were not developed with the implementation of the Ad Hoc Advisory Committee's recommendations in mind. Nevertheless, certain administrative changes proposed by the Committee can be accomplished within the proposed resources. These changes include the development of plans, the refocusing of research and training programs, the development of improved affirmative action programs, the restructuring of patient advisory counsels, and the development of productivity standards.

GRANTS TO INDIAN TRIBES

Question: Are Indian Tribes eligible to receive construction funds through DHEW-HSA Community Health Services to build a tribal outpatient health center? If so, and if the monies did not include ongoing staff, would the Indian Health Service be permitted to place limitations on the tribes' definition of the clinic's service population?

Answer: The Bureau of Community Health Services does not administer any authority which provides for construction grants. However, there are some grant programs of the Bureau which provide support for developing and operating outpatient health centers in designated medically underserved areas or for medically underserved populations which could include an Indian tribe. These grants may include funds for modernization and renovation of existing structures for use in providing outpatient services. Also, we have an agreement with the Farmers Home Administration to make loans available to grantees for construction or addition of necessary health service delivery facilities for populations in rural medically underserved areas. If an Indian tribe were eligible for a BCHS grant, it would be required by law to provide services to all residents of the project's catchment area, including non-Indians.

CHILD HEALTH

Question: It is anticipated that child health will be a topic of intense legislative concern during this Congress. We are concerned that insufficient attention has been paid to evaluating the need for a CHAP program vis-a-vis existing programs that provide child health services. Describe the child health programs that currently exist.

Answer: Under Title V of the Social Security Act, Maternal and Child Health Services are supported through funds provided to States to extend and improve services, especially in areas suffering from severe economic distress, for reducing infant mortality and for promoting the health of mothers and children. Crippled Children's Services are also supported with Title V funds. States extend and improve services for locating crippled children and provide medical, surgical, corrective, and other services and care, and facilities for diagnosis, hospitalization, and aftercare for children who are crippled or who are suffering from conditions which lead to crippling. A portion of the funds are also earmarked for special projects for mentally retarded children.

Other services to children are provided through programs such as the Community Health Centers program, which provides family-oriented comprehensive care in Medically Underserved Areas; the Migrant Health program, which provides care to migrants and seasonal farmworkers, the Family Planning program, which provides both family planning services and medical services to young men and women; and the National Health Service Corps, which provides organized primary health care services in health

manpower shortage areas. A considerable number of the people served in these programs are children and women. For example, in the Community Health Centers program, 41 percent are under age 18 and 25 percent are women of the childbearing age.

Question: What are the inadequacies of these programs which require the institution of the CHAP program?

Answer: The CHAP Program is not being proposed as a remedy to inadequacies of the current Bureau of Community Health Services -- BCHS -- programs. Actually, the CHAP program and the BCHS programs are quite different. The CHAP program is proposed as an improvement to the Early Periodic Screening, Diagnosis and Treatment -- EPSDT -- program, which we have found, under the current law, has certain limitations. The EPSDT program and the CHAP program essentially provide the finances for paying for necessary health services from screening through treatment. The BCHS programs provide the capacity for providing these health services in a setting where case management of comprehensive services can be planned and carried out by appropriate health professionals.

Question: What does CHAP provide that the other programs do not provide?

Answer: The CHAP Program extends eligibility and coverage beyond the current EPSDT Program. Some of the major improvements that this bill would bring, as we see it, would be the establishment of quantitative standards to measure the performance of States in carrying out screening and treatment programs; the extension of eligibility to cover prenatal care and required follow-up services for all low-income mothers and children -- rather than just those eligible for financing of support under the Aid for Families with Dependent Children (AFDC) Program.

Question: When CHAP becomes fully implemented, will the other programs still be needed or will their services be duplicative?

Answer: The CHAP Program will not, in and of itself, expand the capacity to provide health care services. CHAP will assist in identifying the need for services and is available to finance the provision of those services. However, the options available to low-income people to go out and actually receive the services they need are limited primarily because of the lack of health providers within the areas where they live. The BCHS programs offer support for health personnel to be available to provide services in medically underserved areas. Therefore, the programs will be complementary, but not duplicative -- CHAP identifying persons in need of care and providing the financing for low income persons to purchase health care and BCHS programs providing the health facilities where low income persons may go to get necessary care.

Question: If these programs will still be needed, describe the network of child health services as you foresee it.

Answer: These programs will improve health care services to mothers and children through a State-based system of care with the State health agency as the lead agency. Emphasis will be placed on integration of resources such as Titles XIX, XX, and XVI of the Social Security Act and Sections 330, 329 and Title XI of the Public Health Service Act in order to achieve greater impact. In addition, emphasis will be placed on coordination with State and local planning agencies, and Federal programs which can impact on child health. These Federal programs include the Supplemental Food Program for Women, Infants and Children (WIC), Head-Start programs, EPSDT, SSI, etc. Emphasis will also be placed on the development of linkages between State and Title V programs and primary care providers, including Federally funded ambulatory care projects in the State.

The major role of Title V agencies is seen as one of assuring the availability, accessibility, and quality of child health care, and actually serving as a provider of care when other service resources are inadequate or not available. Such a system will require the State Title V agencies to coordinate with all planners and providers of child health care in the State to extend primary care services through better utilization of available resources.

PROVIDER REIMBURSEMENT COVERAGE FOR MENTAL HEALTH PATIENTS

Question: Would HEW support provider reimbursement mandatory coverage for mental health outpatient units freestanding comprehensive mental health centers through HEW's medical reimbursement program to States (Medicaid program)?

Answer: The Department's proposed CHAP legislation covers ambulatory mental health services provided by comprehensive mental health centers (CMHCs) to Medicaid beneficiaries through age 18. The Department is not prepared at this time to require States to provide CMHC services to all beneficiaries as a mandatory benefit. It should be noted that States now have the option of covering clinic services--including CMHCs--in their Medicaid programs.

Question: Will HEW also provide incentives or otherwise encourage non-Federal (private) insurance programs to include expanded mental health coverage in the area of prevention (ambulatory mental health services) as part of their basic medical policies?

Answer: In the past, the Department has not sought to influence the benefit structures of private health insurance programs. However, a mixed public and private approach to National Health Insurance would entail governmental specification of minimum medical and related benefits in private insurance programs. In this regard, the Department is considering a number of coverage issues including ambulatory mental health services.

SUBCOMMITTEE RECESS

Chairman MAGNUSON. The subcommittee will recess subject to the call of the Chair.

[Whereupon, at 12:05 p.m., the subcommittee was recessed, to reconvene at the call of the Chair.]

DEPARTMENTS OF LABOR AND HEALTH, EDUCATION, AND WELFARE AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 1980

THURSDAY, MARCH 8, 1979

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
Washington, D.C.

The subcommittee met at 10 a.m., in room S-128, the Capitol, Hon. Lawton Chiles presiding.

Present: Senators Chiles and Schweiker.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

HEALTH CARE FINANCING ADMINISTRATION

STATEMENT OF LEONARD SCHAEFFER, ADMINISTRATOR

BUDGET REQUEST

Senator CHILES. The subcommittee will come to order.

This morning we will discuss the $20.7 billion appropriation request for the Health Care Financing Administration.

As usual, the medicaid program accounts for the largest share of this agency's increase of $1.6 billion from the $19.1 billion already appropriated for fiscal year 1979; $554 million of medicaid's increase of $1.37 billion is in the form of a requested supplemental for fiscal year 1979. This is becoming a disturbing pattern of underestimating medicaid expenditures, which are sometimes reduced further by the Congress, leading to mammoth supplemental needs halfway through the fiscal year.

The annual increase for medicaid from fiscal year 1979 to fiscal year 1980 is now projected by the Administration at 6.8 percent. If this were achieved, it would indicate remarkable progress in limiting a traditionally uncontrollable program.

Mr. Leonard Schaeffer is the new Administrator of the Health Care Financing Administration. His previous government experience was as Comptroller of HEW.

Mr. Schaeffer, we hope your background in budgetary and fiscal policy will prove effective in dealing with a group of financing programs which have aroused the serious concern of a fiscally-minded Congress.

We look forward to hearing your statement and response to our concerns.

INTRODUCTION OF ASSOCIATES

Would you care to introduce your colleagues at this point, Mr. Schaeffer?

Mr. SCHAEFFER. Thank you. I have been joined here, starting at the far left by Don Nicholson, Director, Office of Program Integrity; Dick Heim, Director, Medicaid Bureau; Mildred Tyssowski, Acting Director, Medicare Bureau; Dennis Fischer, Director, Office of Financial Management; Dr. Clifton Gaus, Director, Office of Policy, Planning, and Research; Dr. Helen Smits, Director, Health Standards and Quality Bureau; and Wilford Forbush, Deputy Assistant Secretary, Budget.

PREPARED STATEMENT

I have a statement that has been submitted for the record.

Senator CHILES. The statement in full will be included in the record and you may proceed however you want.

Mr. SCHAEFFER. I have a few brief comments which I think would be appropriate by way of introduction.

[The statement follows:]

Statement of Leonard D. Schaeffer

Mr. Chairman and Members of the Committee:

I am pleased to have the opportunity to present to you the FY 1980 appropriations request for the Health Care Financing Administration (HCFA).

The FY 1980 total budget is $48.5 billion, an increase of $4.9 billion over FY 1979. A large portion of this budget is financed through a continuing authorization from the two Health Care Trust Funds for Medicare. Our appropriation request is $20.7 billion. This includes $12.6 billion for Grants to States for Medicaid, $8.0 billion for payments to the Health Care Trust Funds, and $132.2 million for Program Management. In addition, we are requesting $836.8 million to be transferred from the trust funds to finance Medicare administration and a portion of research and PSRO activities.

The continuing high rate of inflation has been a major concern in the construction of the 1980 budget. This budget reflects our attempts to restrain inflationary cost increases through regulatory changes and legislative proposals. It also places a high priority on managing programs more effectively to assure the delivery of services to those most in need.

To place these efforts in context, I will first summarize the funding request for the existing programs under current law. Then I will highlight the legislative and regulatory changes, as well as managerial initiatives, which I believe will have a significant budgetary impact.

Grants to States for Medicaid

The Medicaid appropriation request for FY 1980 is $12.6 billion. This is an increase of $812 million over the FY 1979 level or approximately a 7 percent increase. Projected increases in medical care prices account for 97 percent of the increase. The remaining 3 percent increase is primarily attributable to increased expenditures for disabled recipents. We estimate that 23 million beneficiaries will receive health services under the Medicaid program during FY 1980.

Payments to Health Care Trust Funds

The request for FY 1980 for payments to the two health care trust funds is $8.0 billion, an increase of $209 million over 1979, or approximately a 3 percent increase. This request represents payments to the health care trust funds as follows:

(1) The supplementary medical insurance payment of $7.1 billion (an increase of $244 million over 1979), the major component of the request, is for the Federal share of premiums for individuals enrolled in the supplementary medical insurance program. This payment reflects the increases associated with inflation, utilization, and enrollment.

(2) The payment of $696.9 million (a decrease of $37 million over 1979) for hospital insurance for the uninsured reflects the expected decrease in the number of uninsured individuals which is partially offset by increased utilization by the remaining population.

(3) The military service wage credits payment of $141 million (no change over 1979) reflects an annual amount previously determined for the 5-year period beginning in 1977.

(4) The Professional Standards Review Organization (PSRO) activities payment of $35 million (an increase of $2 million) represents reimbursement to the trust funds for the Medicaid share of PSRO hospital review costs.

Program Management

The request for Program Management is $132.2 million in appropriated funds and $836.6 million to be transferred from the Health Care Trust Funds. This combined amount of $969 million reflects a 5 percent increase from FY 1979 funding. This account includes funds for PSROs, Research, Medicare Contractors, State Certification and HCFA Administration:

Professional Standards Review Organizations

By the end of FY 1979, operating PSROs will be established in all 195 PSRO areas. During FY 1980, 10.4 million hospital admissions (an increase of 10 percent over 1979) will be reviewed and limited activity will be carried out in review of long term care and ambulatory care services. Results from the review process are beginning to show a positive impact on utilization and quality of care. According to the 1978 evaluation, hospital utilization by Medicare patients was reduced by 1.5 percent between 1976 and 1977 in hospitals covered by PSROs as compared to hospitals in non-PSRO areas.

The FY 1980 PSRO budget reflects our efforts to limit the administrative costs of the program while expanding its scope and effectiveness. We are accomplishing this through focused review of hospital admissions and other management improvements. Our appropriation request for direct costs of PSROs is $30.6 million; $31.1 million will be transferred from the Health Care Trust Funds, making a total direct cost of $61.7 million in FY 1980, a decrease of $3.2 million from 1979. Hospital review costs are estimated at $90.3 million in FY 1980. This increase has been limited to $5.3 million, or 6 percent over 1979, despite an increase of 10 percent in the number of hospital admissions reviewed.

Research, Demonstration and Evaluation

The purpose of the research program is to provide the information and experience necessary to improve the organization, delivery and financing of health care services. The appropriation request for FY 1980 is $35 million. The total program funding request (including $16.3 million from the trust funds) is $51.3 million, an increase of $19.9 million

over 1979. This request includes an increase of $15 million for long term care research and demonstration funding in response to our concern over the increasing cost of long term care and the need to seek alternative lower cost mechanisms for the delivery of health care services. These funds will be focused on developing an adequate information base, demonstrating alternative methods of financing and delivering services, and developing reimbursement and utilization review systems. An additional $2.4 million is requested to improve data on Medicare/Medicaid beneficiaries, as well as $2.5 million to support demonstrations and evaluations of uniform reporting systems.

Medicare Contractors

The major portion ($661.8 million) of this account funds private contractors who handle the claims processing and auditing functions of the Medicare program. Funding for this activity is financed by transfers from the Health Care Trust Funds. The increase of approximately 4 percent over FY 1979 reflects an 11 percent increase in workload which is offset partially by productivity increases. We estimate that a total of 192 million claims will be processed by the contractors in FY 1980 as compared with 173 million in FY 1979.

State Certification

The goal of the state certification program is to assure that health care providers meet quality and safety standards which will enable HCFA beneficiaries to receive high quality care. This portion of the budget request represents payments to States which carry out the certification program under Medicare. This request has remained at $27.6 million due to improvements made in the efficiency of the survey process despite the increased number of providers requiring certification. The funding for this activity is financed through a transfer from the health care trust funds.

HCFA Administration

The FY 1980 appropriation request for HCFA administrative costs is $166.6 million including $100 million to be transferred from the Health Care Trust Funds, an increase of $9.3 million over 1979. These funds support Federal staff and related costs of administering HCFA programs. The major increases in FY 1980 are: $4 million for improved automated data processing capability: $1.5 million for the consolidation of HCFA's headquarters in Baltimore; and $1.4 million for costs associated with an increase of 90 new positions. The new positions are needed to: process an increased volume of Medicare claims, implement portions of the End-Stage Renal Disease Amendments of 1978, and expand Section 223 cost limits; strengthen management review activities and program validation efforts; and develop uniform reporting systems for health services facilities and organizations.

Managerial and Regulatory Changes

HCFA is carrying out a number of important managerial and regulatory changes. These will reduce fraud and abuse, avoid

unnecessary costs, and hold HCFA expenditures in FY 1980 to $1.1 billion below what they would be otherwise. The changes include:

(1) Improved implementation of Medicaid Quality Control: The MQC system is expected to produce savings by reducing erroneous payments. This system will address errors in (a) eligibility, (b) claims processing, and (c) determination of third party liability ($524 million).

(2) Revision of Reimbursement to Hospitals for Malpractice Insurance: The current method of allocating the cost of malpractice insurance to Medicaid and Medicare patients overstates Federal costs. This proposal will base the allocation of malpractice insurance costs on the actual experience of our beneficiaries in claims filed against the hospital ($310 million total, $40 million Medicaid).

(3) Section 223 Expansion: The extension of Section 223 reimbursement limits to home health agencies and skilled nursing facilities is scheduled for FY 1980. This extension, coupled with revisions in the methods of calculating limits for inpatient hospital services, will reduce Medicare and Medicaid reimbursement to high cost providers ($105 million total, $8 million Medicaid).

Proposed Legislation

HCFA's legislative proposals are designed to promote more efficient delivery of health care services and to extend services to those who are unable to afford adequate health care protection.

The major cost savings initiative is the hospital containment proposal. Our proposal calls for voluntary efforts to hold down the rate of cost increases with standby mandatory governmental controls available if the voluntary efforts fail.

The Child Health Assurance Program (CHAP) will establish incentives for improved performance in the delivery of preventive and primary health care services to poor children. It will also extend Medicaid coverage to an additional 2 million low income children and 100,000 low-income pregnant women.

1979 Supplemental

A FY 1979 Supplemental is requested for Grants to States for Medicaid. Based on the first quarter of FY 1979 and the analysis in the Quarterly Report on the Status of Public Assistance Funds furnished to the Congress on December 1, 1978, we estimate that an additional $554.4 million will be required in FY 1979. This increase reflects both the higher actual FY 1978 expenditures and the higher estimates for FY 1979 based on the most recent information.

Conclusion

Mr. Chairman, that concludes my prepared statement. I will be glad to answer any questions you or Members of the Committee may have.

Biographical Sketch of Leonard D. Schaeffer

NAME: Leonard D. Schaeffer

POSITION: Administrator,
Health Care Financing Administration

BIRTHPLACE AND DATE: Evanston, Illinois
July 28, 1945

EDUCATION: Princeton University, Princeton, New Jersey
B.A., 1969

EXPERIENCE: Administrator, Health Care Financing Administration November 1978 - present

Assistant Secretary for Management and Budget
Department of Health, Education, and Welfare
February 1978 - October 1978

Vice President
Citibank, N.A.
1977 - 1978

Director, Bureau of Budget
State of Illinois
1975 - 1976

Deputy Director
Illinois Department of Mental Health
and Development Disability
1973 - 1974

Management Consultant
Arthur Andersen and Company
1969 - 1973

Senator CHILES. Thank you.

The table on page 15 of the Health Care Financing Administration budget shows the amount of HEW funding for direct medical care for the three major agencies. I'm struck by the fact that even with your new initiatives like the child health assessment program, the share of funds going to children and adolescents will decline from 7.8 percent in 1978 to 7.1 percent in 1980. That follows a 10-year trend.

In terms of the strategy to promote a healthy population, it would seem that children ought to have a top priority and yet the incentives of the system seem to be providing a profitable and expensive service to adults.

What can be done to reverse that trend?

Mr. SCHAEFFER. Our proposal this year on CHAP is a bit different than in previous years. The philosophy behind it has to do with determining what appropriate kinds of services should be delivered to children and, second, the question that you asked—how do we provide incentives throughout the whole system.

In the area of assuring appropriate services, I think I would like to stress the shift in emphasis from a screening approach to a continuing care approach. Screening is an excellent methodology for finding particular conditions, but in an effort to maintain and improve health status, a continuing care relationship is what's needed. So the shift in focus is from screening to continuing care. In terms of incentives, though, there are three areas we want to look at.

The first has to do with providers of services. Currently there really is no great incentive for physicians to provide a comprehensive approach to child health care. What we have done in our CHAP proposal is to create a new category of care—continuing care—and to allow the Secretary the discretion to require prospective capitation funding or other reimbursement for those services. We could then pay a physician not just for the individual procedure, but for maintaining a continuing relationship with that individual.

This need not be a physician. In fact, we would hope that clinics and HMO's would carry on the responsibility as well. But in terms of physician participation, I have met with the American Academy of Pediatrics several times on this matter. They feel these incentives would encourage qualified pediatricians to participate in the child health program.

In terms of States, there's also a problem because currently the administration of assessment and follow-up care services to children is cumbersome and there aren't really any incentives to participate in the present program.

What we have attempted to do is relate participation rates to matching rates so that if a State is able to involve more children and more health care providers, and if they are able to bring better care to those children, their Federal match will increase. In this way, they will be reimbursed for performance. On the other hand, if State performance deteriorates, resulting in the program's failing

to meet the needs of the children, their matching rates would be decreased.

The third area is participation by families themselves. Currently there's a subtle kind of disincentive for families to participate in the early and periodic screening, diagnosis and treatment program—EPSDT. They have to qualify for medicaid, and then they must request EPSDT services. Failure to request those services or failure to pursue certain of the steps in the screening process can mean that the individual child is no longer eligible for certain treatment. The result is the child doesn't get the services.

We feel very strongly, as a fundamental principle of the bill, that all poor children should be eligible for these services and should not have to request them. They can decline them if they want to, but they need not request them in the first instance. Those three approaches are aimed at increasing incentives for participation both financially and in the assistance sense.

Senator CHILES. Well, I note that the increase this year for 1980 over 1979 for children and adolescents would account for 6 percent, adults 10 percent, and the elderly 13 percent—a total direct care average of a 12-percent increase. So there's considerable difference.

Mr. SCHAEFFER. I think there are two issues: one is intensity of services, the younger population does not have the kind of acute needs the other population has. The second issue is participation. We have to convince States and local providers that they have a responsibility to participate in this program, and that has been a problem. That's why we're making these changes.

CHAP PROPOSAL

Senator CHILES. I'm pleased to see that the new CHAP bill indicates as you have said in your statement that you are including some of the amendments that I have offered which were discussed at last year's hearings, including making dental care a mandatory service for children, and allowing the Secretary to set minimum acceptable fees, but I do have some concerns with the proposal.

Why do you propose major expansion of eligibility before you have shown that you can provide adequate service to the children being screened? As I understand it, you would add 2 million new eligible children, 1.35 million children in low income, no AFDC families, and .65, by setting a nationwide low-income eligibility standard of 55 percent of the Federal poverty line.

Mr. SCHAEFFER. This comes from the initial premise that we feel that the Federal Government and State governments have a particular obligation to provide services for poor children. They did not choose to be poor. They did not choose to be in the situation in which they find themselves. At a minimum, this country ought to be able to provide adequate health care for those children.

To a degree the program has not been successful to date in participation by providers and recipients, that is a fact; but we should not penalize the additional children we feel should receive the services.

Senator CHILES. But do we really send the right signals to the poor kids or the parents of the poor kids when we say we're opening up the eligibility or we're going to open up the eligibility

but the service is not going to be there? Wouldn't we be much more credible to be able to do the job where we have now said we have the responsibility and where the obligation is to be able to show that we can do that in a credible way before we take on something else?

Mr. SCHAEFFER. I think there are two parts to the question. One, I don't think we can do the job we would like to do without some of the changes I mentioned in terms of incentives.

Senator CHILES. Well, that's not to say you shouldn't have a CHAP bill. I certainly didn't say that. I'm saying whether you should change part of that bill and go ahead and broaden this eligibility to 2 million children.

Mr. SCHAEFFER. Well, we would like to think, given our mission, that we can do both; that we can improve the program and serve more children.

Senator CHILES. We would prefer that you show us you can do something first and then we'll get on to the other because I think so many times we talk about what we are going to do and we just haven't been credible with what we have talked about.

Mr. SCHAEFFER. I'm not going to debate that point at all.

Senator CHILES. Second, what local mechanism would there be to create a service delivery system? I think medicaid is an empty promise for many kids because there are no doctors available to serve them.

Mr. SCHAEFFER. The entire notion of continuing care which is inherent in the bill is the basis of the issue that you're addressing. In speaking with individual physicians, individual pediatricians, what I have found is that they believe dealing with medicaid on the single visit basis does not afford them the financial support or the opportunity to create this continuing relationship over time with the child and the child's family.

What we're trying to do in our CHAP bill is to create the notion of reimbursing for continuing care. In a clinic, for instance, they would make sure that the family and child realize that care is available for them. In HMO's we could embrace many things in terms of outreach and followup. As we move to the single individual provider, he or she is not as able to do all of those things, but we would hope that the State would take over the responsibility for the case management function.

REPORT ON HOME HEALTH CARE

Senator CHILES. Switching over now to long-term care, when will Congress receive the Department's report and recommendations on home health care which was due October 1, 1979?

Mr. SCHAEFFER. The phasing of that report in terms of when the work was done and when it was due to Congress meant that we had to complete our work at a point in time before the President's budget was finalized. The problem we encountered within the Department was that we had to take a look at the work we had done and the findings we had made to see how they squared with the budget recommendations.

There has been a process, since October when the first draft was completed, of trying to reconcile the results of the report with the

new budget in order to determine what we can do this year and what we can do next year—and to proceed from those findings.

Many of the opportunities for providing for long-term care needs are difficult to implement. We recognize the need for expanded home health care services. The problems we have are the financing of additional home health care due to budget stringency, along with the difficulty of appropriately assessing an individual's need for home care, and providing only those services required to meet that need.

We are aware of some very uneven delivery of home care across the country in terms of quality and appropriateness of utilization. So we are, as an agency, very concerned that we will be able to provide home health care to people who need it. There are multiple kinds of care and multiple kinds of delivery. We definitely think we should be able to provide these varieties of care to our beneficiaries. The other side is how we control and manage home health care.

I think the delay in the report has not been based on any reluctance to support home health care or any belief that it's not necessary. It is attributable to trying to match the timing process for developing the report with the Department's internal budget process.

Senator CHILES. Well, it would seem to me that even if you had to say here are our recommendations, some of these we don't think we can finance right now, with the budget there's no way we can implement these right now; it would still be good if Congress had your recommendations.

Mr. SCHAEFFER. We are trying through the various channels in our organization to get a report to you on a timely basis. I apologize for the delays.

Mr. FORBUSH. I'll try to get the information to the staff this afternoon. I'll try to get that up here.

LONG-TERM HEALTH CARE INITIATIVES

Senator CHILES. When can we expect some initiatives in home care and long-term care from the Health Care Financing Administration and from the Department? In 1977 we got a commitment of more emphasis on long-term care and a focal point on long-term care within the Department and the Health Care Financing Administration was designed to be the place for that focal point.

Other than some research commitments we have made, I don't find any long-term health care initiatives.

Mr. SCHAEFFER. Well, we may see the same situation a bit differently. We see long-term care, including home health care, as an extremely important component principally of the medicaid program but also of the medicare program. We were very grateful for the fact that we were able to add the money last year to do some experiments and demonstrations.

This year we are requesting $15 million in our budget and $15 million in the Administration on Aging budget to conduct broader experiments and demonstrations.

What we have discovered, I think is, there's a continuum of need, but many of the things that are appropriate for the elderly may

not be medical in nature. We can't really extend ourselves in terms of our program into some of those areas because our programs have a medically oriented statutory basis.

The AOA feels very strongly that it has a role of providing some of those social services. What we intend to do with $30 million is to develop a series of demonstrations and experiments which will allow us to evaluate the various ways of channeling people, of assessing needs, of referring individuals to the appropriate services, of making sure those services are indeed rendered in the case management sense, and providing those services.

Experiments in the long-term care area underway right now are expensive. There's almost an open end on all the things you could do, particularly in the social service area. We feel that a $30 million demonstration program is a substantial investment in trying to determine which model is most appropriate.

Again, we're under budget restraints. We have this incredible increase in hospital costs and physician costs, and we just don't seem to have as much as we need to devote to this problem. But long-term care is a high priority as far as I'm personally concerned and I know it's a high priority for the Administration on Aging.

Senator CHILES. Last year this subcommittee asked that $5 million of your research and demonstration budget be earmarked for special demonstrations on long-term care, continuing service systems.

How has that money been spent and what are your plans for this activity in the fiscal year 1980 budget?

Mr. SCHAEFFER. We have been concentrating on trying to build models for local comprehensive referral case management agencies with the funds from last year. We have funded a number of reimbursement and financing projects—you are familiar with some. We have a project in San Francisco, an HMO-type of service delivery mechanism, which includes assessment referrals and also delivery of service.

In terms of the quality of care issue that surrounds long-term care, we have a project in Wisconsin to experiment with new ways of surveying to make sure that high quality care is being delivered. We have a variety of projects that had focused on the medicaid population exclusively, for example in Monroe County, N.Y.; but we are expanding the funding of the projects to include medicare patients.

We are in the final stages of review of another project, the triage project, located in Connecticut.

In 1980 we anticipate expanding demonstration efforts and attempting to fund other models or perhaps in some cases similar models in other locations.

But we strongly feel the need to develop the capacity to deal with long-term care problems. It's just not there.

IMPACT OF ABORTION REGULATION

Senator CHILES. The regulation implementing the current limitation on performance of abortions under the medicaid program has been in effect for a year. Since they were first put into effect in February of 1978, I understand there have been 2,421 abortions

performed on poor women requiring medicaid reimbursement. That's less than 1 percent of the number performed prior to the current limitation. Some 16 States, including the District of Columbia, California, Hawaii, Michigan, Minnesota, Missouri, and Washington, have not had any medicaid abortions.

Is this because the States have resorted to financing them themselves without financial assistance? How would you characterize the regulations?

Mr. SCHAEFFER. I think the situation varies State by State. We have been under rather substantial pressure from Congress to be extremely precise and extremely rigorous in the funding of abortions. Because every State has a different program, we had to go through a rather intensive period of defining and documenting what abortions are eligible for Federal funding. We have regular quarterly reporting from States; we have audited 37 of the States, and we will finish the rest.

What we found is some confusion in some of the States over the definition of what is eligible for Federal funding. We found spontaneous abortions sometimes weren't included in the numbers. We found in some cases that for statistical purposes abortions qualifying for Federal funding were broken out from the other abortions and yet the State accidentally claimed the full amount of the money. So we have been working on cleaning up the data.

I think the number you have is the correct order of magnitude. We have only about four or five States where there's disagreement between the Federal Government and the States. We don't have exact data though. We don't require data on the abortions that are being solely funded by States. I'm really not clear myself and wouldn't be able to comment on that other than to say it varies dramatically State by State. Some States have abortion statutes and regulations that are more restrictive than the Federal Government. Other States are much more liberal. We don't collect that information if they are not federally funded.

Senator SCHWEIKER. On that issue, I see Ohio has had the highest number of abortions. That strikes me as a little bit unusual when New York State, which obviously has a very liberal policy, has had only 55. Ohio has had 386. There must be something done differently in Ohio. I can't conceive that Ohio's law is more liberal than New York's.

Mr. SCHAEFFER. Senator, this is speculation, but I would guess it has to do with the rigor with which the files have been reviewed. In other words, the requirements for federally funded abortions are extremely strict, extremely narrow, and my guess would be that in New York they have done the review of their files very rigorously and have weeded out a lot of abortions that aren't being reported to us. I would guess that there are probably many more abortions in terms of State funding in New York than in Ohio. It's a matter of reporting.

We have underway a program to audit every single State, and I will be able to report to you in detail what we have found. Typically, we have found that there's some confusion over the reporting technique in some States, and we expect that the numbers will change a little bit when the audit is complete.

We report those numbers to Congress on a quarterly basis and revise them as we have done our audits.

OHIO ABORTIONS

Senator SCHWEIKER. Can you give me a special report on Ohio?

Mr. SCHAEFFER. Certainly.

Senator SCHWEIKER. It certainly seems abnormal that Ohio has an abortion rate almost seven times some of our most liberal States. There must be something peculiar about the way Ohio is interpreting the Federal law.

Senator CHILES. Or those other States are just funding it out of their funds.

Senator SCHWEIKER. OK. If you will give me that report.

Mr. SCHAEFFER. The recordkeeping in some States is extremely strict and in some States it is not.

[The information follows:]

We were also concerned about the possibility that the number of abortions for Ohio may be overstated; therefore, Federal and State investigators are reviewing the documentation of claims submitted for payment of abortions in Ohio. Since the investigation is not yet completed, however, we do not know the reasons. We will submit a report to the Committee as soon as the review is done.

HOSPITAL COST CONTAINMENT

Senator CHILES. I'm concerned about your estimated savings for hospital cost control and if we accept your estimates and use the reductions to pay for some of the benefit increases that are going to be proposed, then we've got to be pretty sure these savings are going to materialize.

The Congressional Budget Office thinks that you're overly optimistic for two reasons. First, they don't think you will get full voluntary compliance with your 9.7-percent guidelines in 1979. The higher inflation goes, the worse the situation looks. In addition to reducing your $437 million savings in 1979, lack of compliance will raise the base against which the 1980 increases are computed and reduce those savings.

Second, you assume a full year of standby controls in 1980. CBO points out that your implementations could not begin until after you receive medicare cost reports that are not due until 3 months after the end of each hospital's fiscal year. That means you can't start even enforcing until 3 or 6 months of the year has passed.

These arguments don't reduce the need to enact cost controls, but they could reduce the estimates of savings in this year's budget.

What response do you have to the CBO's arguments?

Mr. SCHAEFFER. On the first point, in terms of accuracy, to estimate national health care costs, given our country's current economic conditions, you must be extremely well qualified or extremely brave. There are well qualified and very brave people who have done the estimates. And while I don't mean to avoid the question, I seriously would refer you to them. It's a very esoteric kind of process. I am convinced that our people have done the best job they could in working with our actuaries to come up with a number. It depends upon your estimates and assumptions about future behavior.

The question about the degree of voluntary compliance is one that can be argued, but we have a series of informed individuals in HEW who made that estimate and a series of individuals in the CBO. I think you would have to discuss it with them.

It's a matter of judgment and erudition in terms of how those factors are calculated.

In terms of the enforcement, though, I think there is a misunderstanding. Cost reports do come in after the end of the year. However, they are settled in a process that determines what the total payment will be for that year and we can indeed make retroactive settlement. The fact that the cost report comes in late doesn't mean we can't change the settlement.

Further, many of the big hospitals, in terms of dollar amount, are in something called the periodic interim payment or payment on a quarterly basis. We can control that payment. We can make sure that payment is not made in excess of whatever the guideline is. So I don't think the timing of the cost reports is going to prohibit us from getting the savings.

HOSPITAL COST CONTAINMENT

Senator CHILES. Well, until you get those reported in you're not going to know whether to trigger the nonvoluntary, assuming we pass the hospital cost containment limitation.

Mr. SCHAEFFER. In terms of an individual hospital, you are correct that we are not going to know. But the hospitals are aware of the limitation and the hospitals if you look at the past behavior, will in the face of a mandatory control, control their spending. That's logical.

Senator CHILES. I'd like you to take the question I have asked you: Can we count on these figures as being solid enough to use those as a means of offsetting some other costs; and give me a written answer in which you take into consideration the point CBO has raised. I want to know whether you can stand on those figures or not.

Mr. SCHAEFFER. I stand on them because they are the figures that HEW has developed, and I have confidence in them. I just don't pretend to be the expert that developed the figures.

Senator CHILES. I'd like the experts who developed the figures to go back and look at the CBO critique and then tell me if they will still stand by them.

[The information follows:]

HOSPITAL COST CONTAINMENT

Question: Will you (Mr. Schaeffer) agree with HEW estimates on Hospital Cost Containment and other savings estimates after reviewing CBO assumptions?

Answer: The figures contained in the President's FY 1980 Budget accurately represent what the Federal savings will be if the President's Anti-Inflation Guidelines are successful. There are precise reasons why CBO estimates on Hospital Cost Containment differ from those we have submitted, respectively, $469 million as opposed to $1.7 billion:

1) Hospital Price Guidelines

HEW assumes that the President's Anti-Inflation Guidelines of 9.7 percent will be effective in calendar year 1979 and 1980. CBO does not believe the guidelines will be observed in 1979, and assumes that in 1980 legislation will be in effect that will allow hospital costs to increase by 10.9 percent.

We do not agree with CBO because we feel that the 9.7 percent target is reasonable and that the hospitals will be successful in reaching it.

2) Magnitude of Cost Increases Without Guidelines

CBO projects that without any hospital cost guidelines or legislation, total community hospital inpatient expenditures would be $65.8 billion. However, HEW actuaries estimate that given that scenario, total non-Federal hospital short-term inpatient revenues would be $67.2 billion. The point here is that HEW savings figures are higher because we project that hospital costs would otherwise be at a higher absolute level without the guidelines than CBO assumes. In other words, the greater the base year costs, the greater are the savings to be gained by limiting growth to a fixed percentage. Furthermore, we are convinced that it is more accurate to project savings estimates on the basis of revenues as opposed to hospital expenditures, because expenditures do not take into account all of the monies which are actually received by hospitals.

3) Enforcement of Standby Mandatory Program

It is certainly true that because of the lag in hospital reporting of Medicare cost data, HEW will not officially know until after January 1980 whether hospitals have avoided triggering in the standby mandatory program. However, that fact will not result in lower Federal savings because the legislation has been expressly designed to take effect as of January 1st. In other words, our new bill (just as its predecessor, the Nelson bill, which passed the Senate last year) requires that each hospital that fails to stay within the national voluntary limit will have its revenues adjusted accordingly beginning with accounting periods after January 1, 1980.

MEDICAID COST ESTIMATES

For the last several years the President's budget has underestimated the medicaid expenditures. That has required extraordinary supplemental needs halfway through the fiscal year. Congress doesn't have any choice when those supplementals come down the pike. We have to raise our budget projections and appropriate the additional funds.

This year you're estimating an increase of 6.8 percent in medicaid costs in fiscal year 1980 from your revised fiscal year 1979 projections. That's less than some projected rates of inflation for the economy as a whole.

Medicaid's cost rose by 11.3 percent for fiscal year 1978 to 1979. When medical care prices generally lead to price inflation, what makes you think that you can hold them down this year? It really doesn't do your process any good at all in our budget planning when we go along and take your figures and they are always wrong and we have to come in and then change everything. I don't think it's really fair to the public either when you tell them the deficit is going to be one thing and outlays are going to be one thing and then you come in in the middle of the year and you change that.

Mr. SCHAEFFER. I think there are several issues involved here. One is the difficulty in making the estimates themselves and, again, that's a function of the expertise of the individuals who are qualified to do the estimating. I think, though, in the case of medicaid estimates, what you will find if you look at just the current law, the difference of opinion between the HEW experts and the CBO experts is $78 million. In a base of $12.6 billion that is a very small difference. If you look at the administrative actions that we propose, the difference of opinion is $376 million. That's the issue.

Senator SCHWEIKER. On that subject, your medicaid budget justification says you predict costs would increase 12.6 percent this year, if not controlled, but that you plan to hold the increase to 10.1 percent for a net 2-percent savings. Last year you predicted the cost would only go up 10.5 percent this year.

Obviously, there's a question whether we're really saving 2 percent or whether you raised your cost increase estimate in order to claim a 2-percent savings. How do you explain this inconsistency?

Mr. SCHAEFFER. Is that 2 percent a function of the hospital cost containment bill?

Senator SCHWEIKER. Yes, I believe it is. I guess the thrust of my question is, you predicted a 10.5-percent increase last year but now you say it's 12 percent, so it comes down to your predicting process.

Mr. SCHAEFFER. I think there are a couple of issues in terms of medicaid estimates that we might want to discuss briefly. Medicare estimating is done by looking at national trends. It's done primarily by the actuaries. The assumption is that you can project economic and utilization trends from the numbers.

Medicaid, however, consists of 53 separate programs. Each program has a different benefit structure. Therefore when you try to estimate nationally you have to make an adjustment for the different State program activities. Further, States are permitted by law, to change eligibility, benefits, and spending practices in their med-

icaid programs during the course of the year. Medicaid estimating is not only a function of economic and utilization assumptions but also involves something very difficult to project, the behavior of the States. I don't know that we have a way of doing those estimates with absolute accuracy.

I can tell you, though, that we are very concerned about the lack of consistency in medicaid estimates over the years. We have been attempting to improve our methodology. We are now estimating both in terms of a model based on national assumptions, and State by State. We are trying to balance one against the other. This is a very difficult thing to do, but we are convinced we are getting better at it.

In terms of the 2 percent you mentioned, Senator, I've been informed that it is a function of different assumptions about both the aged population and overall recipient utilization.

TIME LIMITATION ON MEDICAID CLAIMS

Senator CHILES. In the fiscal year 1979 Conference Report, the Department was instructed to submit with the 1980 budget request a full study of the fiscal and administrative impact at the Federal, State, and local level of the time limitation for submitting public assistance medicaid claims. Where is that study and what recommendations can you make to the committee in this area?

Mr. SCHAEFFER. I'm aware of the regulation relating to prompt payment of claims. We have an NPRM that was published in August and the final regulation will be out in the next couple months. The study, though——

Senator SCHWEIKER. It said it in the conference report language.

Mr. FORBUSH. We have had a little trouble getting the data together. We are a little behind on submitting the study. We will try to get that up to you as quickly as possible. I can say, though, that in general in last year's legislative program we proposed a limit of 2 years on the submission of claims and we are going to submit that legislation again this year and that's what our basic recommendation will be.

Senator CHILES. This committee attempted to require States to submit their claims by the end of the preceding fiscal year. We compromised with the House under the assurance that the Department would submit an analysis of the effects of such a limitation prior to our fiscal year 1980 hearings. We are having the hearings now so we really need that.

Mr. FORBUSH. I do want to make the comment that we do support the time limit on these claims.

Senator CHILES. I hope we have it before we go to conference again.

Mr. FORBUSH. You will have it well before that.

MEDICAID REGIONAL FINANCIAL MANAGEMENT

Senator CHILES. The fiscal year 1979 Senate Appropriation Report went into great length about the necessity of beefing up the regional financial management function. Thirty more positions were provided for the regional financial management of medicaid.

That was in addition to the 100 positions that were previously provided for that purpose.

How many are now performing regional financial management review of the State medicaid report?

Mr. SCHAEFFER. Senator, we hired those 30 people in the last 2 months. That brings the total in terms of HCFA employees to about 200 in financial management and those individuals are in the regions. Their responsibility is to review the quarterly requests for funds from the States and to analyze the trends in those requests.

Again, as I mentioned in response to the previous question, each State has the ability to change its programs and to manage its cash in its own way. What we have found is that we need people at the regional level and sometimes the local level to go over those reports very carefully. We find that that analysis is extremely productive in terms of counseling States as to what they can claim and what they can't claim Further, it permits us to spot things that appear to be inappropriate and to make disallowances in those cases. That particular staff of people and that appropriation are necessary and they are all in place.

Senator CHILES. Do these people report directly to the regional director's office or do they have to go through the regional medicaid bureau?

Mr. SCHAEFFER. They currently report through the regional medicaid director.

Senator CHILES. Wouldn't it be more efficient for the three separate groups of financial managers who investigate the same State reports—medicaid, AFDC and Social Services—to be located in the same office reporting to the regional director?

Mr. SCHAEFFER. In my previous job with HEW I came to the same conclusion. We have created, in the office of a regional administrator a group that would jointly review all of the administrative and all of the common costs between those three programs. Further, we have taken steps—and I believe they are being implemented now—to conduct joint audits and joint fiscal reviews so we don't find ourselves causing problems for the States in terms of multiple visits. I think this is appropriate for the umbrella-type, shared services.

In terms of the specific kinds of functions that are unique in one case to medicaid or AFDC or title XX, those things have to be done separately. We are talking about different services. We are talking about accountability for the quality of care in one case and accountability primarily for eligibility and cash payments in the other. Those things are done separately.

But I support the notion and while I was Assistant Secretary for Management and Budget I got that concept moving. I think you will see it continue to move where we have a single method for all.

FRAUD AND ABUSE EFFORTS

Senator CHILES. Last year during the House appropriations hearings you estimated the following cumulative savings for the Health Care Financing Agency: fiscal year 1978, $10.7 million; fiscal year 1979, $380.4 million; fiscal year 1980, $740.6 million; fiscal year

1981, $1,067.6 million from detecting fraud and abuse. Did you achieve the cost savings for fiscal year 1978?

Mr. SCHAEFFER. I'm not totally familiar with that number. I think I know the 1979 number.

Senator CHILES. Fiscal year 1978 was $10.7 million.

Mr. SCHAEFFER. If those are direct recoveries—Don, do you know that?

Mr. NICHOLSON. I'm not sure if we're right on that number, but we are very close to it.

Senator CHILES. Do any revisions need to be made for your projections for 1979 through 1981?

Mr. SCHAEFFER. Again, I'm not familiar with that particular set of numbers, but the numbers that are in the 1980 budget reflect the programs that are currently underway across a broad range of fraud and abuse and quality control activities.

What we are finding, though, is that there are no experts who are able to predict with——

MEQC CURRENT ERROR RATE ESTIMATE

Senator CHILES. Well, you know, we really need to get this answer because this statement was made at the House appropriations hearings, and that's what our record shows, we want to know. Are you achieving this or are you going to revise that number every year or is it illusory?

Mr. SCHAEFFER. I believe that's a part of the larger program and we can get it for the record. I'm sure we are very close to it.

The point I was trying to make is that in a broader sense what we are finding is we may set a goal for ourselves in one area of quality control and we can exceed it dramatically because we gain the knowledge and the expertise to deal with that problem; in another area our original idea didn't work as well and we may not achieve all the projected savings.

But the bottom line, in terms of savings in 1979, is we are quite confident that our efforts will be successful in terms of dollars. Sometimes when we break it down into the components, we don't make one goal and we overachieve in another. We will get you that for the record.

[The information follows:]

We have reviewed our experience to date in achieving our cost saving targets for FY 1978 and FY 1979 and do not wish to revise the estimated cost saving goals which we have provided with the FY 1980 appropriation request. Our current savings goals add to different totals than the totals we provided to the House Committee last year. The differences stem primarily from our establishment of savings goals in new areas which were not itemized last year, and also from some modifications to the earlier goals based on our experience and accomplishments to date. A table showing our FY 1979 goals and the specific compoments compared to the ones we provided the House Committee last year follows:

FISCAL YEAR 1979 COST SAVING TARGETS

[In millions]

	Original estimate	Current estimate
Fraud and abuse activities	$13.0	$3.6
Program integrity	8.4	4.2
Cost report	9.0	16.0

FISCAL YEAR 1979 COST SAVING TARGETS—Continued

[In millions]

	Original estimate	Current estimate
PSRO	37.0	33.7
MEQC	272.0	265.0
Common audit (proposed legislation)	41.0	.....
State fraud control units	(1)	83.0
Impact of inhalation therapy guidelines	.....	13.0
Malpractice insurance	.....	10.0
Home dialysis	.....	24.0
Total	380.4	452.5

[1] Prior to the estimates submitted with the fiscal year 1980 budget, the State Fraud Control Units were combined with other Medicaid Fraud & Abuse Activities.

MEDICAID QUALITY CONTROL SAVINGS

Senator CHILES. You have estimated a $543 million savings in the medicaid program through better quality controls for payments to providers. Last year the committee funded 125 additional positions for quality control activities. Have those positions been filled?

Mr. SCHAEFFER. Yes, sir.

Senator CHILES. How much did you save in quality control activities in fiscal year 1978?

Mr. SCHAEFFER. We can submit the number for the record. I can tell you about the program, though, what we're trying to achieve.

[The information follows:]

We achieved 18.2 million dollars in fiscal year 1978 in fraud and abuse activities which exceeds the 10.7 million dollar target reported to the House Committee last year. The Quality Control program was planned to begin in fiscal year 1979.

The fiscal year 1978 target of 10.7 million dollars was not associated with quality control efforts; rather it was the goal for fraud and abuse control activities.

Senator CHILES. Well, I'd like to know whether you think you can save twice as much money from quality control in fiscal year 1980 as you anticipate saving in 1979, and I'd like to know what your current error rate is also.

Mr. SCHAEFFER. The medicaid quality control program as initially constructed is based on the experience in the AFDC program and it has three parts: Third party liability, claims processing and eligibility error rate. The program as initially developed came from the AFDC experience. I don't know if our experience would be identical to AFDC or not, but in two of those areas, third party liability and claims processing, we have a substantial headstart on the problem. What we are finding is, through the use of the MMIS systems, we are able to do a very rigorous job of screening. Typically in manual claims processing system there's no way to remove duplicate claims and we are not able to develop what are called profiles of medical practice and select or determine those practitioners that are performing in a manner inconsistent with the general medical approach. By using the MMIS systems and other computer systems we are able to kick out bad claims.

In Florida we have just completed a survey as part of a national survey. They reported to us that they rejected from their system in

calendar year 1978 $26 million for erroneous or bad claims. That's a substantial savings if you were to assume all those claims would have been paid. Perhaps all of them wouldn't have, but the point is that the system is working and working well in that State and other States.

Further, in Florida, they are screening claims as part of a third party liability effort because medicaid, by law, is the payer of last resort as compared with medicare which is the first payer. We find that individuals who may indeed be eligible for medicaid may also have other sources of insurance. We are encouraging States, as energetically as we can to enter into programs to get that third party payment before medicaid pays the claim. In Florida, in that same period of time, their savings were $2 million for third party liability.

There are other good programs in Michigan and in New Jersey. New Jersey saved $9 million.

So we feel that our 1979 goals on third party liability and in claims processing are very reasonable. To the degree we can encourage additional States to develop and implement MMIS systems or other systems that have the capability to screen out bad claims and the ability to do this profiling, we believe that those numbers are reasonable.

Now we may exceed the number we picked for claims processing and may not make the number we picked for third party liability, but they are reasonable and we think we will achieve them.

In the area of eligibility, we must be much more rigorous in the way we get data. Medicaid eligibility is extremely complicated because it varies State by State and it will take us a little longer to determine with precision those particular error rates and how well eligibility screening is done. We have that effort underway as well and our assumptions there are reasonable given the AFDC experience.

Senator CHILES. What is your current error rate?

Mr. SCHAEFFER. The eligibility error rate was estimated at 7 percent, but that is an estimate. We currently have the medicaid quality control system doing a statistically valid sample by pulling actual cases and reviewing them, and we will find out what that error rate is.

You may be familiar with this, but last year the decision was made to revert from this estimating process to a rigorous statistical sample and to take a sample over 6 months and put it in the data processing system.

Senator CHILES. Let us know when you have that figure.

Mr. SCHAEFFER. Yes, sir.

1978 MEQC SAVINGS

Senator CHILES. Do you have reliable estimates for fiscal years 1977 and 1978?

Mr. SCHAEFFER. Estimates. We don't have the system in place and that's the problem.

[The information follows:]

Data from eligibility, CP and TPL reviews for the July to September 1978 period will not be available until June 1, 1979.

FRAUD AND ABUSE SUSPENSIONS

Senator CHILES. This is in fraud and abuse suspension of physicians and other practitioners. Section 7 are medicaid fraud and abuse amendments which require physicians and other practitioners convicted of criminal offenses of participation be automatically suspended from both programs for as long as the Secretary deems appropriate.

How many health professionals have been suspended from these programs to date? Do you have a list of their periods of suspension?

Mr. NICHOLSON. The number is 54, Senator. That number changes constantly as we get new convictions. We not only have a list of who those practitioners are and the length of suspension, but we furnish that list to the State medicaid agencies and medicare contractors so they know that payments should not be made on their behalf. I would be happy to furnish that for the record if you would like.

[The information follows:]

A. Physicians/Practitioners Suspended Pursuant to Section 1862(c) of the Social Security Act (P.L. 95-142)

STATE	NAME AND CITY	DATE OF SUSPENSION NOTICE	LENGTH OF SUSPENSION
Alabama	Jack Randall, M.D. Birmingham	12/28/78	3 years
California	Sara K. Carter, M.D. Los Angeles	1/30/79	3 years
	Louis J. Cella, M.D. Santa Ana*	6/2/78	5 years
	Eugene Morong, M.D. Lancaster	9/19/78	1 year
	Maximo Sarmiento, M.D. San Jose	9/19/78	1 year
	Jimmie Valentine, M.D. San Diego***	8/4/78	1 year
Colorado	Leonard Horwitz, D.P.M. Denver***	5/25/78	1 year
Florida	Kenneth Berdick, M.D. North Miami Beach*	3/24/78	5 years
	Michael Cogan, M.D. North Miami Beach 1/	4/28/78	1 year
	Maxwell Gould, M.D. Tamarac*	7/28/78	1 year
	Mortimer Schaffer, D.O. Bay Harbor Island	11/22/78	5 years
	Arthur H. Manus, M.D. Fort Lauderdale***	8/1/78	1 year
	Norman Pollack, M.D. Fort Lauderdale***	7/28/78	1 year
	Jay O. Schlossberg, D.O. Margate	7/28/78	1 year
	Myron Tietelbaum, M.D. North Miami Beach*	5/24/78	3 years
Georgia	Allan G. Thurmond, M.D. Augusta**	8/31/78	1 year
	John R. Dixon, D.C. Waycross	6/2/78	1 year

STATE	NAME AND CITY	DATE OF SUSPENSION NOTICE	LENGTH OF SUSPENSION
Kentucky	Clarence J. Mills, M.D. Clinton***	8/31/78	1 year
Massachusetts	Abram London, M.D. Wellesley*	8/31/78	1 year
Minnesota	Richard C. Lang, D.D.S. Morris	10/19/78	1 year
Missouri	Ahmed-Samir Abdel-Salam M.D. Bolivar*	5/18/78	1 year
New Jersey	Abraham Chaplan, M.D. Englewood	12/12/78	3 years
New York	Alvin J. Daniels, M.D. Elmhurst	5/11/78	1 year
	Bernard Jacobs, D.D.S. Syracuse	9/1/78	1 year
	Robert Bravato, D.C. Bronx	11/28/78	2 years
	Andrew Messana, D.C. Maspeth	7/13/78	5 years
	Alan Nachamie, D.C. Merrick*	6/13/78	5 years
Illinois	Alvin S. Keith, D.P.M. Evanston	8/9/78	1 year
Ohio	Gordon K. Amsbary, D.D.S. Gallipolis	6/22/78	1 year
	Charles Talbott, D.D.S. Columbus	8/16/78	2 years
	Clayborn C. Taylor, D.D.S. Columbus	8/16/78	2 years
Oklahoma	Allen H. Bunch, M.D. Seminole	6/22/78	1 year
Rhode Island	Melvin Greenberg, D.S.C. Providence*	10/18/78	1 year
South Carolina	Allan G. Thurmond, M.D. North Augusta**	8/31/78	1 year
	Harry Rutherford, D.D.S. Columbia	11/28/78	6 years

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STATE	NAME AND CITY	DATE OF SUSPENSION NOTICE	LENGTH OF SUSPENSION
Texas	Roy Bernstein, D.P.M. Dallas	4/28/78	1 year
	John Bowers, D.P.M. Dallas	5/8/78	1 year
	Robert E. Hausmann, D.D.S. Monahans*	8/17/78	10 years
Washington	James Yu, M.D. Yakima	1/30/79	1 year
West Virginia	John Rhee, D.O. Belle	6/19/78	1 year

NOTE: All suspensions are effective 15 days from the date of the suspension notice.

*Those names preceded by an asterisk are those persons who have requested a hearing before an Administrative Law Judge, Bureau of Hearings and Appeals, to appeal the length of their suspensions. This does not affect the enforcement of the suspension, which remains in effect during the appeal process.

**Licensed to practice in both Georgia and South Carolina.

***Bureau of Hearings and Appeals Decisions see A.1.

****Requested Review By Appeals Council

1/in process of being reinstated.

A.1.
Periods of Suspension Reduced by Bureau of Hearings and Appeals -BHA- Administrative Law Judge.

STATE	NAME	REDUCTION OF SUSPENSION	ELIGIBLE FOR REINSTATEMENT
California	Jimmie Valentine, M.D.	6 months	2/20/79
Colorado	Leonard Horwitz, D.P.M.	2 months	4/12/79
Kentucky	Clarence J. Mills, M.D.	6 months	3/15/79
Florida	Maxwell Gould, M.D.	Decision Upheld by BHA	
	Arthur Manus, M.D.	Decision Upheld by BHA	
	Norman Pollack, M.D.	Decision Upheld by BHA	

B. Persons/Providers Excluded from the Medicare Program Pursuant to Section 1862(d) of the Social Security Act

STATE	NAME AND CITY	DATE OF EXCLUSION NOTICE
California	Robert M. Henry LaJolla (Nursing Home Owner/Operator)	5/18/78
Florida	N. Lois Adams (formerly Lois A. Evans) Longwood	1/5/79
	Complete Breathing Care Orlando	1/5/79
	Boyd D. Evans Orlando	1/5/79
	William B. Evans AKA: Byron W. Evans Orlando (Durable Medical Equipment Supplier)	11/18/77
Massachusetts	Esther S.W. Davidson, D.O. Quincy	3/24/78
	Daniel Dumala Medical Rental & Specialty Corp. Chicopee	2/1/79
New York	Seymour Feldman, M.D. Beacon*	5/19/78
	Eugene Hollander (Nursing Home Operator) New York City	1/24/78
	Elemer Gall Precision Medical Laboratories Mount Vernon	1/15/79
Oklahoma	Maurice D. Lowry, D.C.	1/24/78
Utah	Reuel McPhie 1/ (Nursing Home Operator) Bountiful	9/25/78

STATE	NAME AND CITY	DATE OF EXCLUSION NOTICE
Virginia	Harvey B. Jacobs, M.D. Reston	8/7/78
West Virginia	Leopold Hernandez, M.D. Huntington	11/22/78

NOTE: All exclusions are for an indefinite period and are effective 15 days from date of the exclusion notice.

*The name preceded by an asterisk indicates a hearing before an Administrative Law Judge of the Social Security Administration, Bureau of Hearings and Appeals, has been requested.

1/in process of being reinstated.

C. Persons Whose Suspensions Have Been Withdrawn

C.1. Persons whose Suspensions Pursuant to Section 1862(e) of the Social Security Act have been Withdrawn.

STATE	CITY AND NAME	DATE OF NOTICE
Florida	Michael A. Cogan, D.O. Miami	11/8/78

C.2. Persons whose Suspensions Pursuant to Section 1862(d) of the Social Security Act have been Withdrawn

STATE	CITY AND NAME	DATE OF NOTICE
Utah	Reuel J. McPhie Bountiful	11/30/78

C.3. Persons Excluded Prior to November 1, 1977

STATE		
Puerto Rico	Raul Franceschi-Ruiz	11/1/77
	Reinstated	3/9/78

BLOOD BANK POLICY

Senator CHILES. Several blood banks have routinely charged the medicare program for blood nonreplacing fees even when replacement credits were available to offset these charges. Medicare has made excess payments amounting to several million dollars annually.

GAO has brought this matter to your attention as early as December of 1977, but no action has yet been taken. What action do you plan to take to curtail this practice as quickly as possible and why has no action been taken for more than a year after the situation was brought to your attention by GAO?

Mr. SCHAEFFER. We responded to the GAO audit. I think there is an effort underway in the Assistant Secretary for Health's Office to develop a more comprehensive blood policy.

Ms. TYSSOWSKI. I'm not sure of the status of that, but there is some consideration as to whether there's any need to get a regulation change.

Mr. SCHAEFFER. Can we submit that for the record?

Senator CHILES. Yes; and we would like to know what steps you plan to take to recover past excess payments that were improperly charged to medicare.

[The information follows:]

In our response to the draft of GAO report "Actions Needed to Stop Excess Medicare Payments for Blood and Blood Products" (October 10, 1978), we stated that the preferred manner of dealing with the blood bank problems raised by GAO would be legislation which would permit the Federal Government to have direct influence over the charging and replacement practices of blood banks to assure equal treatment to all patients. Alternatively, provider agreements for participation in the Medicare program might be modified to require providers to deal only with blood banks that agree to adopt acceptable charging and replacement practices which would include allowing Medicare beneficiaries the opportunity to fully replace blood supplied by the blood bank. This alternative method which we are now exploring would be an indirect control and would be administratively complex and expensive. Thus, legislation to clarify responsibilities of blood banks is the desired approach.

As we have no authority under present law to force blood banks to accept full replacement, reasonable provider payments made to blood banks for supplying blood after the blood deductible has been met are proper and not subject to recovery.

PROFESSIONAL STANDARDS REVIEW ORGANIZATIONS—COSTS

Senator CHILES. Critics of PSRO's have charged that the cost of concurrent peer review is greater than it can save in hospital costs and the average cost per discharge has dropped from $17 in 1976 to $15 in 1977. You set a target of $8.70 per discharge by the year 1979. How are you progressing by way of meeting that ambitious goal?

Mr. SCHAEFFER. On the first part of the question, Senator, I don't know if you have had an opportunity to review the evaluation that has been recently completed. I believe that evaluation demonstrates that the cost of concurrent review are offset by the savings achieved and that, at the point in time that study was done, there was a relationship of roughly a dollar spent for $1.10 saved in terms of the peer review. We have been developing with the PSRO's a set of objectives for each PSRO. Further, we have been

trying to encourage and to focus on those areas where they can actually have an impact on improving quality and assuring appropriate utilization in the facility.

By virtue of that objective setting and focusing, we don't anticipate any difficulty in getting down to the 1978 figure.

In addition, I should note that the $15 per case in the evaluation is not fully comparable to our unit cost figure of $8.70. That $15 includes overhead costs applied to each case. Our budget request lists overhead—which comes from appropriated funds—separately from the unit cost per case which comes from trust funds. The 1978 unit cost figure was $13.02. We believe it is realistic to reduce that number to $8.70 in our 1979 negotiations with PSRO's.

Senator SCHWEIKER. I have a question on that.

Senator CHILES. All right. Go ahead.

PSRO PERFORMANCE

Senator SCHWEIKER. In your report you sent to us on the 13th, you make a point that in 29 PSRO's the value of hospital days saved exceeded the cost of carrying out the concurrent review and in five PSRO's these savings were more than double the cost.

Now what this points out, and I think quite well, is that there is obviously a great differential in terms of performance of PSRO's, and my question to you is, why can't we develop some criteria for granting increased support to those PSRO's that are performing well and more closely scrutinize those less efficient PSRO's? I think our approach up until recently has been to lump them all together on the basis that the program hasn't gotten off the ground yet. But the program is now well underway, so what might we do to provide a little momentum costwise to those that are performing?

Mr. SCHAEFFER. I think Dr. Smits, who is responsible for the program, can speak about that.

Dr. SMITS. First of all, we have begun to discriminate among PSRO's as you probably know. The second one will be defunded as of the end of this month. We have relatively limited funds. We have a very tight budget right now and relatively limited funds to reward the good ones. We have tried to set aside a small fund to allow the best PSRO's to continue service in areas like ancillary service. That's only about $4 to $5 million nationally and there's no way you can really get a lot to one PSRO without making it almost impossible for some of the others to function.

1980 BUDGET

Senator SCHWEIKER. Your budget is what in terms of your operation of PSRO's?

Dr. SMITS. This year or 1980?

Senator SCHWEIKER. In terms of fiscal 1980.

Dr. SMITS. We have asked for approximately $48 million for overhead costs and about $90 million for the direct costs with a few additional costs in areas such as long-term care.

Senator SCHWEIKER. What are the comparable figures now?

Dr. SMITS. $51 million for direct cost and $85 million for hospital review.

Senator SCHWEIKER. And there are how many total PSRO's in operation approximately?

Dr. SMITS. There are 192 PSRO's in operation.

Senator SCHWEIKER. Do you mean to say that you wouldn't have in that $130 million figure enough to encourage 15 or 20 or 5 PSRO's to do more?

Dr. SMITS. I'll be glad to submit for the record a detailed analysis of how that breaks down in terms of both overhead costs and review costs. I would remind you, though, that the bulk of that $90 million is spent on the direct cost. That's been cut back to an average day of $8.70 per discharge.

Senator SCHWEIKER. Explain that now. You have been throwing figures at me. What does that mean?

Dr. SMITS. It means that either the PSRO or the hospital to which review had been delegated per case review——

Senator SCHWEIKER. Is $8.70?

Dr. SMITS. Yes. Now that's a very tight figure even using a great deal of focusing. For the cases that are not reviewed at all, where a nurse never sees the chart in the hospital, the cost is about $3 because of costs for the data system which is needed to do the analysis and the cost of quality assurance. That's the average figure. Some PSRO's are higher and some are lower. We tended to put the larger amounts of money where we think there's more return in terms of more expensive hospital costs and more hospital days. So in that sense, we have tried to put the money where the results are, but it doesn't give us a lot of flexibility to reward the best.

[The information follows:]

FISCAL YEAR 1979 AVERAGE OVERHEAD AND HOSPITAL REVIEW ALLOCATIONS

Region	Average overhead costs	Average hospital review costs
Average/PSRO	$263,029	$538,828
Region 1	263,200	334,340
Region 2	240,598	446,641
Region 3	260,545	458,645
Region 4	256,000	643,395
Region 5	264,487	569,462
Region 6	313,500	1,456,184
Region 7	299,714	732,007
Region 8	275,400	357,441
Region 9	262,458	271,575
Region 10	263,000	907,732
Total	43,926,000	89,984,301

REVIEWED VERSUS NONREVIEWED CASES

Senator SCHWEIKER. You said $3 when we don't review the case at all. What do we do for the extra $5.70?

Dr. SMITS. If the case is actually reviewed it costs you more than $8.70. You average it out.

Senator SCHWEIKER. What does it cost you when the case is actually reviewed?

Dr. SMITS. That's hard to say.

Senator SCHWEIKER. Don't you have an average figure on that? You must have an average figure for cases reviewed.

Dr. SMITS. It would depend on how many you focused out and it varies from how intensively the case is reviewed.

Senator SCHWEIKER. I thought you had two categories, one where the PSRO doesn't review the case and one where it does review the case. We certainly ought to have the figures on these two categories because you said the $8.70 was a composite of the reviewed and the unreviewed cases.

Dr. SMITS. The cost in the reviewed cases comes out in excess of $15 but there's a wide spread around that average.

Senator SCHWEIKER. OK, and in a nutshell, what are we getting for the extra $12?

Dr. SMITS. You get someone looking at the chart while the patient is in the hospital. You often get a great deal of——

Senator SCHWEIKER. Someone, meaning what professional person?

Dr. SMITS. Review coordinators. They are usually nurses. They review the chart on the basis of criteria established by the PSRO and approved by us and if they have questions about the case it is referred to someone called the physician reviewer.

Senator SCHWEIKER. What is that?

Dr. SMITS. That is a doctor employed directly by the PSRO or a member of the staff of the delegated hospital who then looks at the case, decides whether he agrees or disagrees that the patient be in the hospital, and then spends a lot of time on the telephone hassling with colleagues trying to get the patient out of the hospital.

Senator SCHWEIKER. So the nurse is the triggering system and then the system is enforced by a doctor?

Dr. SMITS. Yes.

Senator SCHWEIKER. Thank you.

PSRO EVALUATION—SAVINGS

Senator CHILES. The recent evaluations of the PSRO program have mixed results, favorable overall, with good areas making substantial savings. Your budget justification shows that only 6 of the 195 PSRO's will be reviewing ambulatory care services and only 40 of them will be reviewing long-term care. What's the capacity of the other PSRO's to get into these extended areas of review if we gave them the resources?

Mr. SCHAEFFER. Senator, I think the judgment inherent in the budget is that there has been much controversy about the PSRO's ability to impact on both quality and utilization. We think this is the year to demonstrate that they can indeed do that job. We are encouraged by the study that you cited, and the budget provides sufficient funds to do the hospital review properly. The question of expanding to other areas is one that we really have defered pending demonstration of the hospital review success. Those PSRO's that Dr. Smits mentioned that have been successful and have a demonstrated track record are funded to go beyond the hospital setting, but it's our feeling that the program has to demonstrate its impact this year. It can and will.

Senator CHILES. If you're going to reduce the average cost per review, why not plow the savings back into expanding the scope of the review? Wouldn't that increase the incentives to hold down the cost of operating a PSRO?

Mr. SCHAEFFER. It certainly would. I think there are other priorities and our feeling was that this is the year for PSRO's to demonstrate they can indeed do the job in the hospital setting.

PSRO DELEGATED/NON-DELEGATED REVIEW COSTS

Senator CHILES. We see this wide variance between the delegated and nondelegated PSRO's. Of 19 nondelegated hospitals in Los Angeles, there's an average 17.5 percent rate of denial, 14 delegated hospitals in the same area achieved only 2.7 percent rate of denial. What are you doing to encourage nondelegation and do you have any estimates of the savings achieved by delegated PSRO's and nondelegated PSRO's?

Dr. SMITS. I'll have to submit actual savings for the record. We are currently running about 75 percent delegated. As you know, there was a time when there was a strong financial pressure to delegate. That isn't true any more. There's considerable debate within the program as to whether it is possible to do a good job in the delegated setting. That's one of the things we're going to be looking at critically during the coming year. We are discussing it with the National Council in 2 weeks. But in general I would say the pattern is in the direction of the withdrawal of delegation—many PSRO's have already done it—and also in the direction of being more cautious about delegating.

[The information follows:]

We do not at this time have an analysis of actual cost savings by delegation status. The 1978 evaluation indicates that there is no statistically significant difference in the overall effectiveness of review between delegated and non-delegated hospitals. This analysis did not address the actual cost savings of delegated as opposed to non-delegated review.

We are aware, however, that non-delegated review is more expensive than delegated review. Cost information for the four quarters ending June 30, 1978 illustrates this point and I should like to insert that information in the record.

PSRO HOSPITAL REVIEW

	Concurrent review	MCE studies	Areawide costs	Total
Delegated review	$8.24	$1.57	$2.60	$12.41
Nondelegated review	12.47	.67	2.60	15.74
Total review	9.01	1.41	2.60	13.02

Two reasons may explain why non-delegated costs are higher than delegated costs. Delegated hospitals tend to be larger than non-delegated hospitals. Results from the 1978 PSRO evaluation show that, on the average, costs of review are inversely proportional to the number of hospital admissions under review. Hence, larger hospitals would tend to have lower unit costs. Many PSROs that do perform non-delegated review do so for a relatively small proportion of the hospitals in their area. Therefore, they are unable to take advantage of economies of scale in the review process. This makes their unit cost relatively higher.

Given these cost differences, and our interest in monitoring PSRO cost effectiveness with the introduction of the limitation on review costs, we plan to study this topic further. Also, GAO is conducting a study on this issue.

HOME HEALTH CARE SERVICES

Senator CHILES. Going into home health care, many rural areas with large numbers of elderly in need of medical attention can't draw on the professional resources required to establish a certified home health care agency. The only three exemptions allowed for home health care services in such areas are injections, venapunctures and EKG's. These generally are not the most needed medical services. Exceptions allowed for dressing charges, blood pressure monitoring and drug administration seem to make a lot more sense. What was the rationale for choosing these three?

Dr. SMITS. Why don't we submit that for the record?

[The information follows:]

CERTIFIED HOME HEALTH AGENCIES

The Senate Finance Committee Report accompanying the 1972 Social Security Amendments recommended waiver of the normal requirements for covering services rendered "incident to" a physician's services for homebound patients in medically underserved areas when there is a lack of physicians and also home health agencies to provide medical and health care services. This would make it unnecessary to have a physician accompany his or her nurse or technician to a patient's home to supervise the nonphysician services.

There was no program experience with covering a wide range of diagnostic and therapeutic services furnished outside the traditional structure of a participating home health agency or the direct supervision of a physician which would help to ensure the safety and quality of the services furnished to Medicare beneficiaries. Therefore, we decided to begin with coverage of only three services—injections, venipunctures, and EKGs—and evaluate that experience. The American Society of Internal Medicine recommended coverage of these services as those which physicians believed could be performed under general supervision under the circumstances prescribed in the Senate Finance Committee Report. In addition, the nature of these services is such that physician intervention would be required only infrequently. We intended that other services, such as those suggested by Senator Chiles, would be added after adequate experience.

Before that could be done, the Medicare law was amended to provide coverage for services furnished by clinics in rural, medically underserved areas, and services provided by nurse practitioners, physician assistants and nurses as well as services incident to a physician assistant's or nurse practitioner's services. The effect of this amendment is to permit Medicare payment for a wide range of services (in addition to injections, venipunctures and EKGs) as rural health clinic services when furnished by paramedical personnel to patients in their homes without the physician being there to supervise directly. Because, however, there are still medically underserved areas without rural health clinics which would not benefit from this amendment, we intend to proceed with our plans to add more services to the administrative instruction issued pursuant to the Senate Finance Committee Report.

MEDICARE/MEDICAID ADMINISTRATION

Senator CHILES. All right. Your current reorganization proposal seems to be oriented around improved administration in medicaid and medicare programs. I wonder how you handle monitoring of private hospitals if the cost containment bill is passed. That's supposed to be HEW's top priority proposal but we don't see it reflected in the organizational structure.

Mr. SCHAEFFER. The bulk of the work that's required to review the cost reports and to monitor the flow of cash will be done by fiscal agents. We have a contractual relationship with the intermediaries who actually do this. I think what we will be responsible for is enunciating the policies with clarity and providing technical assistance both to our regional offices and to our intermediaries

and we don't anticipate a substantial increase in staff at this point if the bill becomes law as it has been proposed.

There is a request in the 1980 budget for 30 additional people in medicare and 10 of them have to do with the combination of section 223 activities and hospital cost containment. Also, without being indicated on the organizational chart, there is substantial staff attention being paid to our proposal and to others which may come down the road. As the will of Congress is made clear on this issue, we will staff up appropriately.

COORDINATION WITH PUBLIC HEALTH SERVICE

Senator CHILES. I also don't see any improvement in your ability to coordinate with Public Health Service so your financing programs are tied to their service systems programs. The health mission budget presentations have shown the need for that coordination but, again, I don't see any functional divisions that tie your operations to theirs.

Mr. SCHAEFFER. I don't think you see it reflected in the organization chart, but I would like you to know that we consider that an extremely important issue and it's happening in both a personal and administrative manner. We meet once a week to discuss those issues that we feel we can resolve. Further, Dr. Smits meets with PHS staff on matters of medical coverage. We have another group of people that meet on a regular basis with PHS to coordinate our regulations development policy. Currently, we have in HCFA an Office of Health Regulations which is responsible for reviewing the impact of all health regulations, both HCFA and PHS, in terms of cost burden and quality. That is a joint PHS-HCFA effort. If you would ask Dr. Richmond or staff that is involved—these are standing committees by the way—I hope you will hear that coordination on that level has improved.

Again, I would refer to the child health strategy. We are talking about a joint approach to the problem of coordinating all the programs, both PHS and HCFA. I share your concern. I really think that's important.

MENTAL HEALTH BENEFIT

Senator CHILES. I understand your budget includes a proposal to increase mental health coverage by raising the reimbursement fees for psychiatrists to 80 percent of the prevailing physicians' fees. You would also lift their cap from $250 to $750 total expense. With psychiatrists being the most expensive form of mental health care, if you're going to change the law, why not cover the lower cost of professionals like the psychologists and social workers at the same time?

Mr. SCHAEFFER. Well, the proposal that's reflected in our budget comes as a result of the President's Commission on Mental Health. We felt this was the most urgent need and the highest priority. There are a variety of things that we want to investigate down the road, but in terms of 1980 this is the thing to do.

Dr. GAUS. I might add that we are studying in Colorado the question of whether clinical psychologists should be brought into the medicare and medicaid reimbursement system. That study,

covering the whole State of Colorado, will be completed next year; at that time, we would expect to forward those results and recommendations to the Congress as the 1972 amendments require us to do so.

CHILDREN'S HOSPITALS—SECTION 223 LIMITS

Senator CHILES. The fiscal year 1979 Senate Committee Report instructed HEW to except children's hospitals in standard metropolitan statistical areas that are the only facility in the area from the reasonable cost limitations established by section 223(f) of the Social Security Act.

What action have you taken to implement this congressional directive?

Mr. SCHAEFFER. The 223 limits are revised once a year. We are in the process of doing that revision. We have recently issued our NPRM and the limits themselves for public comment. It has not been demonstrated yet in an analytical sense that indeed the children's hospitals have the types of cost structure that would entitle them to that sort of provider status. Further, it may be possible for some nonchildren's hospitals to demonstrate that they can provide the same services at a lesser cost.

Senator CHILES. But since the children's hospitals don't receive medical reimbursement except for renal dialysis, which is funded separately, the reasonable costs associated with these hospitals is not accurately reflected in determining the section 223 limitation for areas in which such hospitals are located.

Do you feel that children's hospitals ought to be excepted from reasonable cost limitations as sole community providers?

Mr. SCHAEFFER. The logic behind the sole community provider idea is that in those cases where there is no alternative—in terms of the service delivery site—and where a good faith effort is being made to control costs, that these limitations should not apply. I don't think it has been documented that that is the case for all children's hospitals in the following sense; in urban areas, for instance, where there's a children's hospital that makes treatment available to children, it may indeed be the case that the more efficient delivery is in the general hospital. But we are reviewing and analyzing that question trying to come up with an analytical solution. We just really don't know the facts.

What has been presented has been a document prepared by the Children's Hospital Association that reflects their costs. The sole community provider idea has to do with alternative availability of services. That is the part of the issue in question.

Senator SCHWEIKER. I'm not clear on that answer. I have read that document. I have seen their breakdown. If they are providing a unique service not provided by others in the community, why doesn't that meet the criteria? What is wrong with the document you cited, which I thought documented it pretty well?

Mr. SCHAEFFER. I didn't mean to say there was anything wrong with it. I just don't think it's complete in its analysis, and it doesn't demonstrate that all the services have to be delivered in children's hospitals. It's quite possible, for instance, that a comprehensive community hospital could deliver the same services, but because

it's more efficient in terms of overhead or, as an example it has specialists who do both child and adult surgery, it may be a lower cost provider. The sole community provider idea is based on the uniqueness.

INTERPRETING THE SOLE COMMUNITY PROVIDER EXCEPTION—

Senator SCHWEIKER. The language is quite explicit. The Committee instructs the Secretary that he's not to interpret the sole community provider exception to include payment for full cost of services rendered by children's hospitals in standard metropolitan statistical areas. How do you get around that? That seems pretty specific. It's an instruction as to how we interpret section 223(f). I don't see how you can say what you did in view of that specific instruction—where's the leeway there? The only leeway I read is in cases where the Secretary finds excessive costs are due solely to luxury or unnecessary expensive services or services generally considered unnecessary for efficient provision. Other than those instances, isn't the language in the Senate report rather specific in providing for exceptions?

Mr. SCHAEFFER. The point I was trying to make is that we have not completed a study which would allow the second part of the instruction to be satisfied—the analysis of costs of children's hospitals versus another service at the site. In other words, the report that's been submitted by the industry documents that their costs are high. The question is, why are they higher? Are they indeed needed? We don't feel we have that information.

Senator SCHWEIKER. Well, it doesn't say anything in our report about a study or judgment—unless there's some kind of a luxury or expensive service provided. Is that what you're studying, cases where there's a luxury or expensive service? I thought the response you gave earlier didn't mention that. It was a matter of whether these services can be obtained in other hospitals at similar costs. Wasn't that your answer? Maybe we'd better go back and hear the answer again.

Mr. SCHAEFFER. At similar or lower costs. In other words, if the community hospital provides the same service at lower costs, then I think you can say that a children's hospital in that particular service category is less efficient and more costly.

Senator SCHWEIKER. OK. What's the status of this analysis you're doing?

Mr. SCHAEFFER. It is underway. We can report to you as soon as it's completed.

Senator SCHWEIKER. When will it be completed?

Ms. TYSSOWSKI. I really can't say exactly, but we can try within 1 month.

Mr. SCHAEFFER. Will that be satisfactory?

Senator SCHWEIKER. Sure. Thank you.

[CLERK'S NOTE.—The information was not available at the time the hearing went to print. It will be provided to the committee when it becomes available.]

PROGRAM INTEGRATION

Senator CHILES. You have been in the process of moving the medicaid and medicare programs for 2 years now. Most of the Washington based medicaid employeed have been moved to Baltimore. Many others have left the agency rather than experience the disruption. Aside from the fanfare and employee grievances, what have you accomplished in terms of more effective administration of these two sort of uncontrollable programs and do you plan to integrate a parallel program operations along functional lines rather than maintaining the autonomous identity that currently exists?

Mr. SCHAEFFER. The medicare-medicaid programs are very different programs in terms of both philosophy and target groups. If you look at the administration of those programs they have common elements. And if you look at the complaints and concerns of providers and beneficiaries, many of those complaints and concerns center around those administrative burdens. Particularly in the case of providers, there's concern over the different ways that the same service has to be reported or documented for payment under one program versus the other.

So the goal of our efforts to become more efficient is to integrate those administrative functions and to make them as simple and as standard as is possible in order to insure quality of care to beneficiaries. By making it easier for providers to deal with us, we make it easier for beneficiaries to gain access to needed services. That's the benefit to be gained here. A 35-mile separation between the medicaid and medicare programs may not seem like very much, but if you add to it the different histories of the program, if you add to it the complexity of the history of what happened over time the separation has an impact. I think the two programs solve similar problems in different ways. The way we view health care and the way your mission budget is organized is to look at the health component and not to look at the two separate programs. If you look at it as a health delivery system I think you've got to have a functional arrangement of the administrative services. That's what we're trying to do. We have 20 integration projects. All of them may sound easy and even kind of silly, but they are incredibly important.

If the uniform bill, for instance, were just one common form that every physician or provider could fill out and understand, if that form were processed in a proper manner, I think we would find physician participation increasing. A uniform bill helps with timely payment. We could pay people on a timely basis because every provider knew what his reimbursement rate would be when he got the check. I think we would get increased participation.

So our goal in terms of functional organization is to make the program as simple as possible so that it's possible to increase participation by providers, and thereby increase access and service to beneficiaries.

UNIFORM REPORTING SYSTEMS

Senator CHILES. Going into your uniform reporting requirements for hospitals, I'm concerned about the potential impact of your

proposed regulations to implement a uniform reporting system for hospitals. While I know these are required by law, I'd like to be convinced they don't impose an undue financial or administrative burden on the hospital. We have been hearing from hospital administrators in Florida and even modest estimates indicate that the proposed guidelines would have the hospitals submitting about 25 percent more information. One hospital with less than 500 beds estimates that it would cost them as much as $143,000 to convert to the uniform reporting system, plus an additional $47,500 to maintain it.

I'm concerned that every time we identify an abuse we try to solve that problem by adding tons of paperwork requirements. It seems particularly ironic that we are trying to implement the uniform reporting necessary for efficient hospital cost containment by significantly increasing the cost of reporting to providers. This cost has to ultimately be passed on to the Government and other third party reimbursers and the paying patients.

What is your estimate of the cost and the benefits of uniform reporting?

Mr. SCHAEFFER. Let me begin with a broader issue because I think you struck it——

Senator CHILES. Why don't you begin with answering the question?

Mr. SCHAEFFER. $8,000 to $9,000 per hospital.

Senator CHILES. $8,000 per hospital?

Mr. SCHAEFFER. We have a study underway right now to determine what those costs would be. If the actual cost in terms of that study are higher, we will take a new look at the report.

Further, there's an extended comment period. The burden will indeed be reduced in response to the specific suggestions to do that.

Senator CHILES. I didn't want to cut you off.

Mr. SCHAEFFER. That's all right. The point is, we are in a dilemma here. We have absolutely inadequate statistics on hospital costs in this country. If we were anything but the Federal Government we would be ashamed of how little we know. We cannot compare the cost of X-rays. We cannot compare the cost of meals. We cannot compare costs across hospitals. We do not know, period.

By the same token, we are in an environment where Government is accused in many cases of overregulating.

Senator CHILES. We understand the Office of Management and Budget has rejected the amount of detail required by the initial guidelines and has requested that the cost-benefit analysis be done before the final regulations are issued.

Mr. SCHAEFFER. I'm not aware that they have rejected it. In fact, my staff recently met with the President's Regulatory Council and I was informed that the decision was made to wait for the results of the study we have underway. I want to make the point that there are two issues here. One is uniform accounting and the other is uniform reporting. The Congress decided that they did not want uniform accounting. You agreed that we needed uniform reporting. We issued a NPRM that clearly states our willingness to reduce the burden and level of detail as long as we get the necessary information. The question is how and when. I have extended the comment period beyond the usual 45-day period, to 90 days. We

have been working with the industry to reduce the detail and that burden, yet meet the legislative intent and operating data needs for HCFA programs.

I don't think we're ever going to get the situation where everybody is going to agree that these particular forms are to be filled out in a particular way. Each hospital has a different way of going about its business.

Senator CHILES. Could you provide the committee with a copy of any analysis of your plans in reducing the detail?

Mr. SCHAEFFER. Yes. We have a project underway to analyze the burden and the cost. That project will be completed before we come out with the final regulation and again we will submit it publicly and we will take into consideration the suggestions that flow from that study.

UNIFORM REPORTING COSTS

Senator CHILES. This $8,000 per hospital, is that the initial cost or is that an annual cost?

Mr. SCHAEFFER. That's an average annual cost.

Dr. GAUS. It's a one-time cost implementation.

Mr. SCHAEFFER. But you're going to find wide variations. For instance, a hospital may decide they want to redo their accounting system, which is not required by this. It's not uniform accounting that's required, but if you redo your accounting system, obviously the cost is going to be a little higher. Also, there are exemptions for small hospitals for annual reporting. There's a briefer report.

Dr. GAUS. Let me comment on preliminary findings from the study which will be completed in about four weeks. The data from about 20 percent of the hospitals in the sample show that even where as part of implementing the reporting system the hospital intends to completely redo their whole financial management system, the high cost in that case was in the range of $40,000 to $45,000, nowhere near the $140,000 that was cited earlier, and in some cases the cost for implementing the reporting system alone was as low as $200. So the range is great. We are absolutely convinced that the $8,000 per hospital is a high estimate of the potential cost.

Mr. SCHAEFFER. Again, it depends, Senator, on how much of the cost you want to ascribe to Federal regulation. There was a study done in New York which indicated that there are 165 reports required from the hospitals by Federal, State, and local regulators. That sounded very frightening and we were very concerned. But if you look into it, many of the reports are things the hospital would need in any case such as a balance sheet, financing reporting, some breakout of costs. One of the problems we have—I spoke to the American Hospital Association on this—is to try to reduce the level of anxiety and the rhetoric flowing back and forth and work on this, so that we can get straight the minimum required for accountability to the Federal Government.

REQUIREMENTS OF EXECUTIVE ORDER 1204

Senator CHILES. Executive Order 1204 requires agency heads to review issues involved in significantly new regulations and to ex-

plore alternative approaches before developing guidelines. What alternatives have you considered as to the levels of detail contained in the first regulation? What other alternatives are you considering now?

Mr. SCHAEFFER. Dr. Gaus has been responsible for extensive conversations and discussion with the industry.

Dr. GAUS. Years ago when we started developing the system we consulted with a number of States, looking at the range of reporting requirements. In some cases the States had lesser requirements than we finally included. In some cases, more. The process we went through in developing this proposal—the System for Hospital Uniform Reporting—SHUR—included a detailed look at each of the items requested and the kind of utilization to be made of those items. In the end I think the proposed system was a compromise, a compromise between what various accountants and regulators of cost might need as opposed to the cost of collecting that data.

With respect to the specific Executive order you cited, we determined that the estimated total national cost for implementing the system of about $35 to $70 million was not sufficient to require the formal regulatory analysis.

Since that time, we have met with OMB and the President's Regulatory Council and the Council decided that further action was not needed until we completed the HEW study. We did promise to forward to the Council a copy of the study we are doing to assess the cost of implementing the system, and agreed that if indeed that study showed a much higher implementation cost than we initially estimated, further public comment would be needed and also that substantial revision of the system might be required.

Mr. SCHAEFFER. New York State has implemented a system very similar to SHUR as a mandatory requirement. So has the State of Washington. As a result, there will be a lot of experience and informed comments that come in as to what kind of changes we should make. We hope, therefore, to change the system for the better. There's no attempt to shove this down somebody's throat. We just have to get the bare minimum of data.

Senator SCHWEIKER. Well, I'm confused here. The Regulatory Council decided that no formal regulatory analysis was needed of this?

Dr. GAUS. Yes.

Senator SCHWEIKER. I'm flabbergasted. Here are 500 pages—that were sent out on the reporting system which the hospitals have to comply with—500 pages, completely changing many of their procedures in reporting. They claim that it will cost over $100 million for hospitals to implement this, and yet you say there was no formal regulatory analysis done. I don't know what the Executive order was meant to cover if it doesn't cover a case like this. How can you change a fundamental thing like a reporting system for hospitals across the country and say that doesn't have a regulatory impact? What was their basis for saying that no regulatory analysis had to be done on this regulation?

Dr. GAUS. My understanding is, first of all, the guidelines in HEW have a threshold of cost impact of around $100 million. If it's higher or estimated to be higher, the formal analysis is required. The Regulatory Council has decided at this time not to require

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regulatory analysis pending the outcome of our study. They want to be sure that the cost of implementing the system is in the range we have estimated.

UNIFORM REPORTING—FRAUD AND ABUSE FOCUS

Senator SCHWEIKER. Let me read from an Ernst & Ernst report. This law was called the Medicare-Medicaid Anti-Fraud and Abuse Amendments, and I think those of us who supported it—and I was one of them—did it on the basis that we were emphasizing fraud and abuse. Now Ernst & Ernst points out—and I just want to quote from them—"in support of this premise, we offer the observation that in the more than 500 pages of the SHUR manual, there's not a single reference to using the reported information to detect fraud and abuse." Maybe I'll just read further. "Based on our review and analysis, we believe that SHUR was not designed to satisfy the primary purpose of the act, the detection of fraud and abuse."

My question is, in view of the thrust and intent of the act to control fraud and abuse—which is the reason my colleagues and I supported it—why isn't there some emphasis in this reporting system on fraud and abuse?

Dr. GAUS. I think the system does focus on it. It doesn't directly reference it in here, but clearly in New York State, the Special Prosecutor's Office has found that indeed more detailed and uniform cost data does permit screens to be done of that data to detect various purchasing practice abuses, as well as fraudulent activities. So I think it will indeed——

Mr. SCHAEFFER. Without the ability to compare the cost and the practices in one hospital to those in another hospital, we are not able to segregate our problem hospitals. The hospitals don't see it that way. They see themselves as being forced to do it one way when they'd rather do it a different way. The compromise we tried to hit was not to require a change in accounting practices but to let each hospital have its own accounting system and report the results of its accounting system in a uniform manner to us so we can compare. That's really how you spot excessive costs and excessive utilization.

Senator SCHWEIKER. When will you have this report?

Dr. GAUS. Our study will be finished in about 4 weeks. We will at that time make it available publicly and there will be 1-week public comment—1 week left in our public comment period on the whole system. We would hope that the industry, as well as other interested parties, will comment on the proposed regulation and on the study as well.

[The information was not available at the time the hearing went to print. It will be provided to the committee when it becomes available.]

Mr. SCHAEFFER. We are trying, Senator, to do this in a public and a cooperative manner. The restraint on us is the law itself and I don't think, in all sincerity, we are attempting or intending to increase the burden for its own sake. I think if you talk to some of the professionals you will get that sense that there's been an extended effort to try to improve the quality.

MEDICAID MANAGEMENT INFORMATION SYSTEM

Senator SCHWEIKER. I understand that several States administer their Medicaid program with the aid of a computerized information system known as MMIS. It's also my understanding that MMIS has the capability to effectively detect cases of possible fraud and abuse and that increased Federal funds are offered to the States to evolve such a system.

How many States have a computerized system in operation?

Mr. SCHAEFFER. At the moment, there are 23 States with MMIS systems. We plan to have 33 States at the end of this fiscal year. By the end of 1980 it's our hope that we will have about 40.

Senator SCHWEIKER. And are the capabilities of detecting fraud and abuse substantially increased by the new system?

Mr. SCHAEFFER. Yes; where the systems are applied rigorously. One of the problems we have had in the MMIS development process is that certification of an MMIS system has been made on the basis of the technical specifications of the system and how well it's programed and not on how well it's applied. One of the major changes I have made is to begin a system of recertification to make sure that States are indeed applying all the capabilities of the system.

Senator SCHWEIKER. Well, you anticipated my next question, because some of the criticism is that they are not fully utilizing their potential.

Mr. SCHAEFFER. I believe that's correct.

Senator SCHWEIKER. And the GAO people have said that in the past you have been certifying systems that probably you shouldn't be certifying. You're saying that you're taking another look at that procedure?

Mr. SCHAEFFER. I'm saying we have changed the procedure. I'm saying we agree with the observation and that we have taken very aggressive action to try to turn that around.

Senator SCHWEIKER. Are you following GAO's suggestions for checking State approval procedures for State systems?

Mr. SCHAEFFER. We are using their suggestions but we are trying to get the States involved. We have a National Technical Advisory Committee. Some of the States have been extremely creative and have done an extremely good job in a number of areas. We are trying to use the expertise of the States to get a medicaid program that's a Federal-State partnership, and one of the techniques we are trying to use is to let States lead other States in terms of how to improve the system.

I agree with the thrust of the GAO comments and I think we are on the way.

Senator SCHWEIKER. There's a statutory requirement that medicare-medicaid systems be compatible but States are failing to coordinate the two systems. What are you currently doing to enforce the requirements that these systems be compatible?

Mr. SCHAEFFER. Part of our functional alignment is aimed at consistency, and further, these 20 integration projects I mentioned are the basis for that kind of activity—the uniform accounting bill, the uniform coding conventions, common definitions of things as simple as a claim. Senator, in different States a claim is defined

differently, a bill is defined differently. We have to compose or develop some kind of common understanding so we can deal with all the States.

SWING BED CONCEPT

Senator SCHWEIKER. Some areas with shortages of long-term care beds have a surplus of hospital beds which could be converted to long-term beds to reduce shortages. What role could HEW play in encouraging such facility conversions and what plans do you have?

Mr. SCHAEFFER. Well, one of the things that we are very interested in is the "swing bed" concept.

Dr. GAUS. We are completing projects in four States where we actually have permitted the hospitals to use their acute care beds for long-term care purposes. Of course, we provide lower reimbursement because the services are not as intensive as on the acute care side. Those demonstrations are almost completed and the administration has endorsed this concept in legislation. In fact, you may recall, Senator, last year it was part of the Talmadge amendments in the Senate.

Mr. SCHAEFFER. It's an excellent idea and we'd like to see it work.

REASONABLE COST LIMITS

Senator SCHWEIKER. You have authority under section 223 of the Social Security Amendments to set reasonable restrictions on medicare-medicaid payments. What are you doing at the present time and what do you plan to do in terms of using that authority?

Mr. SCHAEFFER. 223?

Senator SCHWEIKER. Yes.

Mr. SCHAEFFER. We have just issued an NPRM and revised the cost limits for this year. Basically we have taken into account a number of the comments we have received over the course of the year, so the process for allocating costs and limits has been cleaned up very substantially. We have taken out some of the capital cost and institution costs, and those rules are out for public comment right now.

UNNECESSARY SURGERY

Senator SCHWEIKER. I have just one more question, Mr. Chairman, and then I'll turn it back to you.

Unnecessary surgery has been reported as a major factor in spiraling health care cost. First, have you done any studies in terms of the prevalence of unnecessary surgical costs; second, what steps, if any, have you taken to require second opinions for surgery paid for by medicare or medicaid as part of our cost containment program?

Mr. SCHAEFFER. There are three areas that we are pursuing in terms of the incidence of procedures that are inappropriate. One is the second opinion program that we have initiated, which is a national program that essentially tries to promote the use of second opinions through a public education and awareness program. Second, we have set up a system of toll-free lines and referral services which makes available to anybody who wants a second opinion the name and address of a person qualified to give the second opinion. We have some demonstrations underway. In New York, we have found, in our demonstrations, that 30 percent of the

decisions that are given by the initial physician are disagreed with by the second opinion physician.

Now we have a lot of followup to do to see what the actual patient behavior is when this occurs. Does the patient say, yes, I want it, or, no. What does he or she actually do? Those studies are underway.

We also are going in to our second round of trying to publicize through newspaper and television publicity the fact that this second opinion program exists.

The second area where we have tried to reduce unnecessary procedures is in limiting surgical reimbursement. We issued regulations which identified 26 procedures for surgical diagnoses for which routine reimbursement for physicians was discontinued, and now these are not paid for unless there were very special circumstances.

The third area is with the PSRO's. They are really on the frontlines reviewing in each hospital the profiles of the kinds of procedures that have been done, spotting excessive utilization, spotting behavior that's not within the norm and going in in the way Dr. Smits described to you and getting physicians to question whether that surgery was necessary.

So we feel we have an aggressive program.

Senator SCHWEIKER. Thank you.

UNIFORM REPORTING—AMERICAN HOSPITAL ASSOCIATION

Senator CHILES. The American Hospital Association I understand has asked its members to provide for them what they expect their costs to be in having to implement the regulation. That's a 6,000 membership as I understand. Are you going to follow that or do you have any provision to provide us with copies of those costs?

Dr. GAUS. I'm aware they have asked. I have not seen any of the results. The study we are doing is much more extensive than the American Hospital Association survey. The study is being done by an accounting firm which goes into the hospital and not only questions the administrator about what he and his staff think implementing the system will cost, but actually runs through the whole process of implementing the system, simulating every step.

Preliminary findings from our study indicate that in many cases the estimate of costs of actually implementing the system is far less than the administrator initially thought. I think we do want the AHA's numbers and we do want to look at how they were developed. Certainly we will take them into consideration as we make our final decisions. I should point out that the empirical study we are undertaking was designed and implemented after the American Hospital Association had concurred with the methodology.

Mr. SCHAEFFER. We have asked the AHA and its membership to comment on the regulations. In terms of the benefit side, in California, where there's a system which is like SHUR, one of the things that was discovered is that when you have the ability to compare the cost of common services that there's a wide variation. We found a variation of 200 percent in the cost of a meal, for instance. There's no medical component, there's no expertise in

preparing a nutritious lunch which accounts for this variation in cost, providing the nutrition that you think is appropriate, but there was over 200 percent variance across California hospitals. There was over 600 percent variation in the cost of the same X-ray or same lab test.

I think there's concern on the part of the hospitals that we are going to find extremely wide variations and that, because of the pressures on us to reduce costs, we are going to say let's reduce that variance and let's not reimburse for the most expensive costs. I think that is a great concern.

QUESTIONS SUBMITTED FOR RESPONSES

Senator CHILES. We have some additional questions that will have to be answered for the record. If you would please try to answer those and return them to us along with the hearing transcript within 7 working days, that would be helpful to us.

[The following questions were not asked at the hearing, but were submitted to the Department for response subsequent to the hearing:]

Questions Submitted by Senator Chiles

MEDICAID ESTIMATES

Question: Your latest Quarterly Report on Public Assistance Programs indicates a shortfall of $165 million in Fiscal Year 1979. Due to the FY 78 surplus of $158 million, it will not be necessary to increase your pending supplemental request. Fortunately, the General Counsels of HEW and the GAO are of the opinion that surplus Fiscal Year 1978 Funds can be used for the purpose since the shortfall is created by unpaid FY 78 costs.

Isn't this a good example of why Public Assistance Appropriations should have extended availability to prevent lapsing funds at the end of the year?

Answer: Yes, this is what we are proposing to do in our latest Quarterly Report to the Congress on the Status of Public Assistance Appropriations. We believe it is appropriate to have the ability to use a given year's Medicaid appropriation to reimburse a State for its expenditures in that year even though the State reported the expenditures after the fiscal year ended.

MOVE TO BALTIMORE

Question: How much will the planned move of the Health Care Financing Administration's --HCFA-- employees to Baltimore cost?

Answer: Our best estimate of the total cost of the move is 2.7 million dollars.

Question: What savings do you anticipate from this move, both in dollar terms and improved program productivity and efficiency?

Answer: No specific dollar figure has been developed. The relocation will lead to the consolidation of staff doing similar work, increase the exchange of information between employees, and facilitate the integration of Medicare and Medicaid activities. These improvements will assist HCFA in carrying out its responsibilities in a more responsive and cost effective manner.

The improved communications, reduced travel time, and co-located management which will result from the relocation will more than offset the cost of moving the employees involved. Specifically there are currently 20 integration projects now underway. All are designed to improve the administrative efficiency of our programs to insure quality of care to beneficiaries. Having staff co-located will greatly assist in their completion.

Question: How large a staff will HCFA maintain in Washington?

Answer: The staff that will remain in Washington will include a small core from each of the Agency's operating bureau's, as well as personnel from staff units whose proximity to the Secretary's Office, OMB, other components of DHEW and to the Congress is required. The number is approximately 200.

Question: How many employees will have offices both in Washington and Baltimore?

Answer: Approximately 15 senior executive staff will maintain offices in both locations.

Question: How many employees have chosen to leave HCFA rather than move to Baltimore? Are you planning to fill any of these vacancies?

Answer: About 300 employees indicated that they did not want to relocate to Baltimore. All vacancies resulting from this process are being or will be filled.

STANDARDS FOR PRODUCTIVITY

Question: Secretary Califano said (at an Institute of Medicine meeting in October, 1978) that HEW plans to develop standards to evaluate the productivity of the nation's health care system. What are these standards? Have they been developed?

What is your timetable for their development?

What aspects of the health care system will be evaluated?

What HEW office is developing these standards and evaluating the health care system as a whole?

How will these standards tie in with planning guidelines or with HEW policy goals?

Answer: As the Secretary indicated in his October 26 speech before the Institute of Medicine, the Department has established productivity standards for the primary care centers which it funds. These standards have only recently been issued to grantees and the Department is initiating an evaluation of their implementation.

In his speech the Secretary also stated his intention to request the National Health Planning Council to develop a systematic approach to setting productivity standards. The Council's Subcommittee on Productivity and Health Technology has made the Secretary's request its major charge for 1979. Under the leadership of Dr. Philip Caper, Vice Chancellor for Health Affairs at the University of Massachusetts, the Subcommittee has initiated a one-year examination of health care productivity and productivity assessment in the United States. The Subcommittee will look at productivity in three areas: institutions, manpower, and technology. In each of these areas the Subcommittee will produce a description of the state-of-the-art in both the public and private sectors and recommendations to the Secretary on what, if anything, should be done to enhance productivity assessment, to change planning guidelines and standards, change reimbursement formulae etc., in order to provide incentives to increase productivity.

In adddition, the new reporting systems which we are developing in response to Section 19 of P.L. 95-142 will be extremely valuable in evaluating institutional productivity. These reporting systems will, for the first time, provide the Department with comparable cost, utilization, billing and discharge data for institutional providers.

The Notice of Proposed Rulemaking governing implementation of the System for Hospital Uniform Reporting, or SHUR was published in the January 23rd Federal Register. We anticipate that final regulations will be published later this year, with implementation in FY 80.

HEALTH MAINTENANCE ORGANIZATIONS

Question: I understand that HCFA has recently funded a number of projects in the HMO reimbursement area.

When will these projects be completed and shouldn't HCFA wait until the results are in before recommending legislation to change the present HMO reimbursement formulas under Medicare and Medicaid?

Answer: On September 30, 1978, the Health Care Financing Administration approved seven demonstration contracts that will develop and test prospective risk reimbursement under Medicare and Medicaid to HMOs. Awards were made to the following organizations: Blue Shield of Massachusetts in Boston, Fallon Community Health Plan in Worcester, Massachusetts, Health Central in Lansing, Michigan, InterStudy in Minneapolis, Kaiser in Portland, Oregon, Kitsap Physicians Services in Bremerton, Washington, Marshfield in Marshfield, Wisconsin. The contracts are scheduled for four years of operation.

These demonstration projects are clearly not a substitute for legislative action. While the demonstrations are proceeding, we expect to continue discussions with the Congress regarding the adoption of improved methods of reimbursement to HMOs under the Medicare and Medicaid programs. These demonstrations will provide the Department with further operational experience with a broad range of alternatives and will enable the Department to expeditiously implement legislative changes made in this area.

DUPLICATION WITH OTHER AGENCIES

Question: Could you contrast HCFA's research and evaluation strategy with the present activities of the National Center for Health Services Research and the Office of the Assistant Secretary for Planning and Evaluation, particularly with regard to cost containment issues?

Answer: The research and demonstration mission of HCFA is geared directly toward expanding our understanding of the Medicare, Medicaid and Professional Standards Review Organizations--PSRO--programs so as to improve the operating effectiveness of these programs with respect to cost and quality of care. The results of HCFA studies, experiments, demonstrations, and evaluations provide essential information used by decisionmakers in considering proposed policies and/or legislative changes which would affect the delivery of health care services to HCFA program beneficiaries. The National Center for Health Services Research and the Office of the Assistant Secretary for Planning and Evaluation are responsible for ensuring that comprehensive and systematic efforts are made to develop new options for health services delivery and to develop means for monitoring the performance of the health care system.

With respect to cost containment issues, NCHSR will pursue a general research focus on the development and implementation of structural reforms of the health care system and the provision of incentives for more cost-effective utilization of health care resources. HCFA, on the other hand, will develop specific economic knowledge about hospital reimbursement behavior in order to respond to policy questions regarding changes in reimbursement systems and how these systems can improve the Federal and State third-party payment programs. HCFA projects will support the efforts to develop and compare alternative reimbursement systems in anticipation of broader Federal authority for controlling inflation in hospital costs and demonstrate and evaluate the hospital cost containment potentials of alternative prospective payment and rate setting systems.

RESEARCH AND EVALUATION

Question: I am interested in your proposal to start a new large national survey, which you are calling the "Medical Care Utilization and Expenditure Survey." Will you tell us what this will provide that your current Health Interview Survey and Medicare/Medicaid data do not?

Answer: The Medical Care Utilization and Expenditure Survey -MCUES- will provide data on the utilization of all health care services, "health care costs," sources of payment, and social and economic characteristics of health care systems users, for a sample of Medicare and Medicaid beneficiaries and the U.S. population as a whole. Information on Medicaid users will be obtained from four large States which account for a major proportion of Medicaid expenditures. These data will be collected from a standing panel which will be interviewed five times over a one-year period.

This survey will provide certain critical information which cannot be obtained from any other source. Medicare and Medicaid administrative records are limited to services covered by those programs; they do not provide social and economic data and cannot identify all sources of payment. On the other hand, MCUES will provide information on non-covered services not available from administrative records, such as aged Medicare beneficiaries spend over $1 billion on prescription drugs which are not covered by the Medicare program. In addition, there are no person-based Medicaid records at the Federal level which means that most of the MCUES data cannot be generated from existing Medicaid statistics.

The Health Interview Survey -HIS- is primarily interested in prevalence and incidence of illness, "disease," and disability, and provides information regarding the extent of health insurance. However, HIS does not follow individuals over time and cannot provide a longitudinal perspective on costs," utilization," sources of payment, and relationship of these items to social and economic characteristics. In addition, HIS does not make separate estimates for the Medicare and Medicaid populations.

Question: Would you reduce those surveys to pay for this one?

Answer; HCFA could not reduce the current level of resources needed to maintain Medicare administrative records since these are needed to manage the Medicare program. On the Medicaid side we are

now expanding our efforts to develop a Federal reporting module in which the States would provide detailed unit record information on a sample of claims so that we can improve the management and policy direction of the Medicaid program at the Federal level.

The Health Interview Survey is a Public Health Service activity and The National Center for Health Statistics' plan to continue HIS while developing MCUES suggests that they need both surveys to fulfill their legislative responsibilities.

Question: Why can't you answer those questions by a series of limited sample studies, instead of putting a new large survey in place?

Answer: MCUES is based upon a longitudinal survey--a panel design--which will provide data on the total U.S. population and the Medicare and Medicaid programs. A panel survey is one which follows the same group of people--households--over an extended length of time--in this case, one year. Repeated interviewing is necessary in the period of observation because people cannot recall their utilization experiences over long intervals. An annual period of observation is required so that utilization and payment can be linked, and because financing arrangements, such as cost-sharing, are typically predicated on a calendar-year basis. Limited surveys cannot provide the range of data for the groups mentioned above nor the flexibility to link person-based data across time.

LONG-TERM CARE STUDIES

Question: In the long-term care area, will the costs of any of the projects designed to coordinate medical, social and housing needs be shared by other agencies or other HEW components (e.g., Housing and Urban Development, AOA, and Office of Human Development Services)?

Answer: The HEW budget includes long-term care research and demonstration initiatives for both the Health Care Financing Administration and the Office of Human Development Services. In the development of project design, HEW will be addressing the full range of long-term care issues and coordinating the involvement of other HEW components such as SSA and PHS as well as other departments such as HUD and possibly the Veterans Administration.

HEW has already initiated a joint demonstration project with HUD designed to provide congregate housing facilities for the mentally disabled. HUD is financing the construction of the facilities and HEW is assuring the provision of appropriate services through the liberal use of Section 115 waivers.

LONG-TERM CARE

Question: The area of long-term care remains an area of fragmentation within the Department of HEW. Please supply the Committee with information indicating what are the various offices that deal with long-term care and how these offices relate to one another so as to avoid duplication and achieve effectiveness and consistency.

Do you anticipate any organization changes relating to long-term care?

Answer: The subject of long term care is one that cannot be separated from the program responsibilities of our major operating components, the Health Care Financing Administration, the Public Health Service, the Office of Human Development Services, and the Social Security Administration.

As the primary payer of long-term care health related services, HCFA has the lead responsibility for policy development in such areas as standards for participation, reimbursement, and coverage. HCFA has an active research and demonstration program. Our activities in this area are being closely coordinated with OHDS and with the involvement of the Assistant Secretary for Planning and Evaluation. The Public Health Service, through several of its components, is also involved in research in long-term care. HCFA and PHS have begun a series of monthly meetings to coordinate their work in this area. Finally, the data gathering activities of the SSA research effort is linked to long-term care because of Supplemental Security Income and Disability Program linkages with HCFA's Medicare and Medicaid programs. Staffs of these agencies have shared their research plans and are discussing joint efforts.

There are no plans to reorganize long term care responsibilities in HEW. The Assistant Secretary for Planning and Evaluation assures that the kind of coordinating activities described above are in fact taking place.

VOLUNTARY COST CONTAINMENT

Question: What is the Department's position on the Medical industry's "Voluntary Effort"?

Answer: The industry's announced goal is to achieve an average annual price increase in hospital expenditures of 13.6 percent in calendar year 1978 and 11.6 percent in 1979. According to data developed by the American Hospital Association -AHA-, it appears that the providers have achieved the first part of their goal from January to December 1978. Costs increased at a rate of 12.8 percent.

However, HEW believes that this goal is too inflationary and should be rejected in favor of the President's hospital price guidelines of 9.7 precent, which were promulgated last December. We know that hospitals can bring their inflation to a level below 12.8 percent if their commitment to reducing waste and improving their management practices is sincere. In fact, nearly one-third of the nation's hospitals were living within a 9.7 percent rise in 1977.

Question: What do you estimate were the savings under that effort for Medicare and Medicaid in 1978?

Answer: The Department of Health Education and Welfare believes that the voluntary effort has had some effect on lowering costs; however, we cannot single out the magnitude of that effect because of the existence of other confounding factors which are:
-1- the threat of mandatory federal cost containment legislation;

and -2- the existence of mandatory hospital rate setting programs in nine states.

Question: HEW has the authority under Section 223 of the Social Security Act to set prospective cost limits for Medicare and Medicaid that can vary by types of hospitals, their geographical location, and so on. Right now, you're only using this authority to limit routine costs. Couldn't this existing legislation provide the authority for an effective hospital cost containment program that would be less politically vulnerable?

Answer: Yes, present authority under Section 223 of the 1972 Amendments can be used to obtain more effective hospital cost containment for Medicare and Medicaid. We have already proposed stronger regulations based on this authority. However, the flaw in this approach is the lack of authority to prevent hospitals from shifting the burden of Medicare "savings," to the general public. True cost containment, to benefit all patients, does require new legislation.

PROFESSIONAL STANDARDS REVIEW ORGANIZATIONS

Evaluation

Last year at this time, you had just completed an evaluation of the PSRO program which indicated that PSROs were not effective in reducing hospital utilization. I understand you have completed another evaluation of the program.

Question: Does this new evaluation show that PSROs are doing any better?

Answer: We are much more optimistic now about the future success of the PSRO program than we were a year ago. We recently completed an extensive evaluation of the PSRO program's performance in 1977. I am happy to report that this evaluation indicates that PSROs do indeed have an impact on reducing unnecessary hospitalization:

> For 1977, PSRO review resulted in a 1.5% reduction in Medicare hospital utilization nationwide compared to non-PSRO areas.
>
> Eighty-one of the 96 PSROs studied showed a relative decline in hospital utilization.
>
> In 1977, the 96 PSROs studied saved about $50 million from the elimination of unnecessary hospital days, compared to the cost of performing this review of $45 million.

We are particularly encouraged by the documentation in this evaluation of the significant progress in the program between 1976 and 1977, which occurred even before the start of our management initiatives to improve the performance of PSROs. We believe that the savings reaped from PSRO review relative to operating costs should continue to grow in the future for several reasons:

> Older PSROs are more effective. The evaluation results suggest that PSRO performance improves as PSROs mature.

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Reductions in hospital utilization not only provide significant short run cost savings, but create opportunities for larger savings in the long run, as unnecessary hospital beds are closed.

Our management improvements are designed to increase the impact individual PSROs have on reducing inappropriate utilization and improving quality in their areas.

We have taken steps to reduce the cost of performing PSRO hospital review by over 30%.

Question: Did your evaluation show that some PSROs were much more effective than others?

Answer: The aggregated results for the 96 PSROs included in the evaluation showed that overall, PSRO review resulted in a 1.5% reduction in Medicare utilization, with a cost benefit ratio of 1.10:1. However, significant variation existed in the performance of individual PSROs:

Eighty-one of the 96 PSROs studied saved days of care relative to non-PSRO areas;

Twenty-two PSROs had relative utilization reductions in excess of 3.4%;

Thirty of the 96 PSROs had benefit-cost ratios greater than 1;

Fifteen PSROs had benefit costs ratios in excess of 2:1;

Two PSROs had benefit cost ratios in excess of 10:1.

If we can maintain the performance of those PSROs that did well in the evaluation while improving the performance of those PSROs that did not show a positive impact, then we will substantially improve the overall performance of the PSRO program.

The evaluation was limited to gross utilization changes for Medicare patients. In addition, we have other indicators of positive performance by PSROs, for example:

Impact on expensive hospital days rather than on gross utilization;

Impact on unnecessary days in communities where necessary use is rising;

Impact on overuse of specific troublesome procedures--i.e., tonsillectomy and adenoidectomy--;

Impact on quality;

Preparation of sanction reports;

Participation in the control of fraud, abuse, and waste activities; and

Collection of special data for planning purposes.

Performance

Question: What are you doing to improve the performance of PSROs?

Answer: We are committed to improving the overall performance of the PSRO program. To do so, we recognized last year that we would need to concentrate on ways to improve the ability of each PSRO to impact on the particular quality and utilization problems in its area. We have implemented a PSRO objective setting process to accomplish this:

Each PSRO is now required to identify specific utilization and quality problems in its area, such as high lengths of stay, high surgical rates, or definable problems in quality of care. We have provided statistics to PSROs to assist them in this task.

The PSROs working with Regional Office personnel then develop specific measurable performance objectives to deal with these problems. These performance objectives are made a part of the grant award made to the PSRO.

Monitoring of the PSRO's performance will be made against the objectives they set.

PSROs that fail to set objectives will not be renewed for funding. PSROs that can't demonstrate that they attempted to achieve their objectives will be considered for defunding.

Our target is to have acceptable performance objectives established in all PSROs by June 1979.

The objective setting process allows us to monitor the performance of PSROs on the basis of outcome measures rather than process measures. It also forces the PSROs to allocate their review efforts to those utilization and quality problems where they can have the greatest impact.

Question: How do you monitor the performance of PSROs and what do you do with PSROs that do not perform acceptably?

Answer: The Regional Office has the primary responsibility for monitoring the performance of PSROs. Regional Office personnel conduct assessments of PSROs, track deliverables with particular emphasis on objectives, and make routine visits to PSROs. There is also monitoring conducted by the Medicare intermediaries and Medicaid State agencies, and financial audits are conducted by the HEW audit agency. All of these monitoring efforts provide input to the Regional Office to assist in the refunding process.

There is also a formal process of PSRO assessment coordinated by the Central Office; however, not all PSROs are assessed every year. Under this procedure, an assessment team comprised of Federal staff, PSRO staff from around the country, and State Medicaid personnel review the past and current performance of PSROs according to a set of assessment standards which reflect the latest expectations of HSQB and "state-of-the-art" regarding ideal PSRO performance.

As poor performing PSROs are identified through our various monitoring and evaluation processes, the PSROs are being offered the opportunity to improve. Failure to improve will result in termination.

To date we have terminated one PSRO for poor performance in its financial management responsibilities -Tennessee -.

A second PSRO has been informed of our intent to not renew its contract because of poor performance of programmatic responsibilities -Calumet -.

In addition a number of PSROs have been notified of performance deficiencies that can lead to termination, if not corrected.

Number of PSROs in Operation

Question: How many PSROs do you have in operation now?

Answer: We have 182 conditional PSROs and 10 planning PSROs. Three designated areas in the country do not now have a planning or conditional PSRO:

Illinois VII - This should be funded as a planning PSRO within the next month;

Tennessee - This conditional PSRO was terminated in November 1978 as a result of financial mismanagement. A replacement PSRO has not yet been funded;

Nebraska - We have been unable to find a group willing to become a PSRO in Nebraska;

One other PSRO has been advised that we will not renew its contract as of the end of March -Calumet -.

In addition, we believe that significant economies can be made by reducing the number of small PSRO areas because this will result in a decrease in overhead expenses, particularly personnel costs:

We will examine the feasibility of consolidating PSRO areas in those instances where a PSRO is terminated for failure to perform;

We are also exploring with small PSROs the idea of their voluntarily consolidating with other PSROs that are adjacent to them, if such consolidation will result in a more cost effective review system;

We are uncertain of the administrative steps that would be required to mandate the consolidation of existing PSRO areas

in those cases where the individual PSROs do not want to consolidate. We are examining this issue now to see whether additional legislation would be helpful to accomplish consolidation.

Fully designated PSROs

Question: Are any of these PSROs fully designated?

Answer: None of these PSROs are fully designated. A conditionally designated PSRO may be fully designated only if it is substantially carrying out in a satisfactory manner all the required review responsibilities. We anticipate that 20 PSROs will be fully designated by the end of FY 1979 and 60 more PSROs will be fully designated by the end of FY 1980.

Question: Do you feel legislation is needed in order to fully designate more PSROs?

Answer: Our legal interpretation of current legislative provisions is that PSROs must be performing some degree of long term care (LTC) review in order to qualify for full designation. Because of past and continuing program funding limits, and the fact that LTC review procedures are less well-defined than acute care review, relatively few PSROs are now conducting LTC review. Many PSROs, for instance, will have completed 48 months of conditional designation by June 1979, without having been funded to perform any LTC review.

Given these circumstances, legislation to modify the current LTC review requirement or to provide for separate full designation for various categories of review (i.e., acute care, LTC, ambulatory) might be advisable.

Cost Overruns

Question: Do most of your PSRO grantees spend their entire grant?

Answer: The negotiation and award of funds to PSROs is based on the best estimate of the PSRO for implementation of their plan for the subsequent year of operation. The Health Standards and Quality Bureau and appropriate HCFA Grant Officer conduct an evaluation to assure the reasonableness of proposed costs based on the plan and the PSROs actual expenditure for the previous year. In most cases, the PSROs will have a small (i.e., less than 1 percent of budget) carryover, due to the need to assure adequate management funds. In a few cases, PSROs have a greater percentage of unexpended funds due to unforseen implementation delays and other scheduling problems during the contract grant period. Reasons which accounted for major carryovers were lack of State approval for PSROs to conduct hospital or LTC review and a slower implementation schedule for review, once approval was received.

Question: What was the total amount unspent and overspent in FY 1978?

Answer: In FY 78, $60.3 million was available for direct funding to PSROs. Of that amount, approximately 9 percent or $5.5 million was not expended by the PSROs. Primary reasons for carryovers by PSROs were lack of State approval for PSROs to conduct hospital and particularly LTC review and a slower implementation schedule for review, once approval was received.

Medicare and Medicaid Facilities

Question: On June 8, 1978 HEW issued in the Federal Register a set of specifications for new standards that would apply to Medicare and Medicaid facilities. What are your current plans for moving ahead with the project of rewriting the regulations?

Answer: On June 8, 1978 the notice in the Federal Register announced the schedule of public hearings to be held on the need for changes in standards. The hearings were concluded in August of 1978. It is anticipated that the Notice of Proposed Rule Making will be published in the Spring of 1979.

Question: Did the more than 600 comments you received on the proposed regulation result in any major philosophical changes in the direction that you want to go?

Answer: The public hearings that generated the 600 plus comments were held with the view toward determining what changes, if any were required in the regulations. We have approached this area with questions, not with preconceived policy we wanted to implement. The public comments received have therefore been instrumental in the development of the policies that will be set forth when the Notice of Proposed Rule Making is published.

MEDICAL CARE SURVEY

Question: The justification refers to a Medical Care Utilization and Expenditure Survey that will be carried out cooperatively between HCFA and the National Center for Health Statistics. How will this cost-sharing arrangement work?

Answer: The total cost for the Medical Care Utilization and Expenditure Survey--MCUES--over a three-year period is $17.3 million. HCFA's share is $11.5 million or 66.5 percent, while NCHS' share is $5.8 million or 33.5 percent. NCHS will be the lead agency for the MCUES survey, but HCFA will have equal responsibility and authority in all decisions relating to the contract. The cost-sharing by component is provided for the record.

Cost Sharing for MCUES
(in millions)

MCUES Component	HCFA	NCHS	Total
Household Survey	$4.6	$5.8	$10.4
State Medicaid Survey	5.4	0	5.4
Administrative Record Survey	0.5	0	0.5
Medical Provider Survey	1.0	0	1.0
Total	$11.5	$5.8	$17.3

HOSPICES

Question: Do you anticipate making any legislative recommendations in the coming months regarding hospice care?

Answer: We at HEW are deeply interested in the hospice movement. Early last fall we named a Special Assistant to bring coherence and focus to all our efforts in this area. Through her efforts, HEW components have developed a coordinated approach to study the issues of care for the terminally ill. The Health Care Financing Administration is in the process of implementing a hospice demonstration program to gather data on the cost and use of hospice care by Medicare/Medicaid recipients. The Health Resources Administration is involved in the education and training of hospice personnel and the National Cancer Institute is conducting demonstrations which focus on the care and outcomes of hospice patients.

In early June, HEW is sponsoring a national conference on the care of dying patients. Its purpose is to inform the public about the hospice concept and care; to advance the knowledge of health professionals, private insurers and labor and business officals about care for the terminally ill; and to explore approaches to private sector funding including insurance coverage of hospice services.

As we begin to learn from our efforts, we will explore the possibility of making changes in our programs to eliminate some barriers to reimbursement. However, in doing so, we will need to ask these questions:

> Do we have an adequate base of knowledge and experience to assess the economics of hospice care?
>
> Can we provide federal assistance without weakening private and voluntary support?
>
> How do we foster quality and prevent abuses without over-regulation?
>
> How do we encourage a program of care, yet discourage the building of unneeded new facilities that drive up costs?

We expect some preliminary answers to these questions in FY 81.

NURSING HOME SHORTAGE

Question: I understand that surveys by PSROs in New York and Washington, D.C. have revealed serious shortages in nursing home beds for hospitalized Medicaid and Medicare patients awaiting placement. The result is a huge waste of money on patients who no longer need to be in hospitals. Have you taken any steps to assess the extent and cost of this problem nationwide? If not, do you have any future plans to do so? I also understand part of the problem of over-extended hospital stays may be due to delays in reimbursement for those nursing homes that do have available beds. What specifically is the cause for such delays and what are you doing to correct this situation?

Answer: We are well aware that a problem exists with Medicare and Medicaid patients awaiting transfer from hospitals to nursing homes. Our best estimate from PSRO data currently available is that problems in placing Medicare hospital patients in skilled nursing facilities account for about 2.5 percent of hospital days paid under Medicare. There is considerable variation in the extent of the problem from area to area as well as the causes. We are taking several actions to ameliorate the situation.

For rural areas where there are few nursing facilities, we are supporting legislation which would allow underutilized hospital beds to be used for nursing care. This concept of "swing beds" has been found successful in HEW demonstrations in Utah, Texas, Iowa, and South Dakota. We are examining how this concept could be effectively used in urban areas with placement problems as well. In both cases, we expect to modify usual hospital reimbursement rates so that payments will be commensurate with the lower level of services needed by these patients.

We have also been supporting legislation for grants to aid hospitals in converting excess acute care beds to nursing care use, and have been examining ways to change reimbursement policies and the Medicare/Medicaid conditions of participation to provide additional incentives for conversion.

The health planning agencies and the PSROs are now working together on the local level to determine the extent of placement and nursing home bed shortages and to develop plans for alleviating the problems. Through our research and demonstration programs, we are actively exploring alternative ways of providing long term care. In some projects, we are seeing nursing home candidates successfully discharged to their homes with a well organized, managed array of home based services.

Regarding the question of whether delays in reimbursements may be responsible for placement problems, we are not aware of any such instances. We believe that there may be cases where the implementation of "cost related" reimbursement, as required by Section 249(a) of PL 92-603, has caused dissatisfaction with Medicaid levels of payment in some States. We are concerned about the effect of payments on access to care and continue to encourage States to ensure adequate participation of facilities in Medicaid.

LONG-TERM CARE RESEARCH

Question: Will the projects proposed for funding in the long-term care area provide any data that could be used to evaluate the reasonableness of State Medicaid "cost-based" reimbursement plans for nursing home care?

Answer: PHS and HCFA plan to implement a project to assess the impact of Sec. 249(a) of PL 92-603, which requires States to reimburse nursing homes on a reasonable cost-related basis, on the cost, use, and quality of nursing home care.

Using data primarily from the National Center for Health Statistics bi-annual nursing home survey, the project will study changes in ownership patterns, bed size, utilization, and costs and quality of care for nursing homes in selected States.

MEDICARE

Question: 86 percent of all people over 65 suffer from some form of chronic disorder, yet the Medicare program is geared toward payments of short-term acute illnesses. Only 38 percent of all medical bills faced by the elderly are paid by Medicare.

How can the Administration and Congress gear Medicare towards the treatment of chronic illness without excessive institutionalization of the elderly?

Answer: For the past year, HEW has been working at the many issues involved in community based, long term care of the chronically ill as well as the disabled and the frail elderly. Solutions to the complex public policy issue of long term health and social support to those in need will not be developed easily.

We believe that before current programs are expanded in a major way and/or new ones created, large scale demonstrations are required to study the impact of a variety of comprehensive systems of delivering care to the chronically ill. We do not want to implement systems that might destroy the current support given by family and friends. Methods need to be found to assist patients and their families in getting access to the range of health and social services that are needed. We need to develop mechanisms to prevent abuse and assure quality of service developed. The determination of measures of entitlement and eligibility for publicly funded services, as well as the development of private third party coverage in this area, will require much study.

The nation's health care system and the payors of care-public and private-have long been oriented toward acute care and institutional caré. We need to explore very carefully the provision of and payment for long term care in the community.

RESEARCH

Question: In the Hospital Reimbursement area, HCFA research has had a negligible impact on Medicare and Medicaid program policies. For example, it does not appear that HCFA research has led to any viable alternative to the existing retrospective cost reimbursement system. Despite HCFA's efforts to develop a uniform reporting system for hospitals, there is still no government-operated system for monitoring increases in hospital costs in a timely and accurate manner, nor is such a system contemplated.

Could you provide specific examples of Medicare or Medicaid program policies that were changed as a direct result of HCFA research?

Answer: I believe the HCFA research and demonstration program has had a very significant impact on Medicare and Medicaid reimbursement policies. A summary of select demonstration projects which have had impact on these Federal programs is being provided for the record.

You also asked about the development of uniform reporting systems for monitoring hospital costs. Demonstration activities with State rate-setting organizations showed that adequate data does not exist to make sophisticated regulatory decisions. As a result the Department supported passage of provisions for uniform cost, discharge and bill reporting, in amendments to the National Health Planning Act and the Fraud and Abuse Bill, P.L. 95-142. These systems will be the basis for the health data programs for the 1980s. In addition, we have been encouraging States to implement these uniform systems. New York State has already done so. A Notice of Proposed Rulemaking was published in the Federal Register on January 23rd regarding adoption of the System for Hospital Uniform Reporting, or SHUR. Final regulations on SHUR are scheduled for later this year. SHUR will provide a standarized national system for the timely monitoring of hospital costs.

You also may be interested in the effectiveness of our hospital cost containment activities. Through our demonstration authorities we have supported a number of State hospital cost control efforts. These State demonstrations have been an invaluable source of information about how to control hospital costs. Furthermore, these demonstrations are beginning to show the benefits of prospective rate determination for Medicare and Medicaid. By conservative estimates, $16.5 million in Federal savings will result from two State rate setting demonstrations in FY 1979 and an estimated $80 million in Federal savings from State demonstrations expected to be operational in FY 1980.

INSERT FOR THE RECORD

Examples of demonstration projects which have had an impact on the Medicare and Medicaid programs.

- Ambulatory Surgery: The favorable experience demonstrated through waivers given to six free-standing ambulatory surgical centers for coverage of ambulatory surgery has directly encouraged and supported legislative initiatives for coverage of this cost effective benefit.

- Swing Bed: As a direct result of this demonstration involving approximately 100 hospitals in Iowa, South Dakota, Utah and Texas, several bills have been introduced authorizing the use and reimbursement of long term care services provided in underutilized, rural acute care hospital beds where there is a shortage of long term care beds.

- Durable Medical Equipment: Information and experience gained from the implementation and evaluation of alternate reimbursement systems for Durable Medical Equipment, carried out in 11 States under HCFA waivers, were instrumental in the passage of Section 16 of P.L. 95-142 to authorize this alternate reimbursement method.

- Second Opinion Surgery: The information gained from two demonstrations of second opinion programs (New York and Michigan) was incorporated into the Department's second opinion program.

- Fraud and Abuse: A demonstration was funded with the Office of the Special Prosecutor in New York State to utilize a team approach in prosecuting Medicaid fraud and abuse. This activity was a precursor to Section 17 funding of State fraud and abuse units in P.L. 95-142.

- Prepaid Health Research and Development: HCFA has funded the State of California to develop rate setting techniques and assess the quality of care measures in health maintenance organization settings. We expect these methodologies to be considered for application by other States and Medicare to health maintenance organizations. Other capitation demonstrations will focus on reimbursement and coverage systems that promote effective and efficient utilization of health services financed by the Federal programs.

- Talmadge--Expanded Application of 223 Limits: As a result of a series of research and demonstration activites (Yale University and University of Washington) it has been demonstrated that more sophisticated and potentially more powerful classification techniques exist for hospital reimbursement limitations. These newly developed approaches are being considered as we assess alternate 223 approaches to setting more stringent, yet equitable, limits on hospital reimbursement. Such an approach has been a feature of legislation sponsored by Mr. Talmadge in both the last and current Congress.

- As a result of HCFA research and demonstration activites, legislative changes have been recommended to change Medicare and Medicaid reimbursement for the cost of hospital malpractice insurance. This change would base malpractice reimbursement on historical risk instead of current premium charges. The estimated savings is $310 million per year.

Based on these research and demonstration results, the situation was discovered and policy changes are being implemented to correct the situation. Savings are estimated to be $100 million annually.

- Medicare Economic Index for Physicians: As a result of research and demonstration activities a survey of physicians' practice costs was instituted to collect data with which to refine the Medicare Economic Index. The data obtained from this survey have already been useful in refining the Index so that it reflects more accurately the breakdown in physicians' expenses. The FY 1978 and 1979 Indices used weights derived from the 1975 survey data and the FY 1980 Index will use weights from the 1976 survey data.

- Hospital Based Physicians' Compensation: Research and demonstration studies of hospital based physicians received national media attention in the summer of 1977. These studies documented the six-figure compensation levels of hospital based phsicians. This was a major factor leading to the amendments of the Administration's hospital cost containment bill on hospital based physicians' reimbursement.

- Changes in Procedural Terminology Systems: An intramural study of the effects of the 1969 California Relative Value Studies upon Medicare Part B costs showed that changes in procedural terminology systems can have a major impact on Medicare outlays. This led to a regulation whereby carriers may not change the procedural terminology and coding system used to determine Medicare reimbursement, until they can demonstrate a net advantage in using the newer system according to criteria specified in the regulation.

DISTRIBUTION OF RESEARCH FUNDS

Questions: The budget justification for the Health Care Financing Administration lists 10 major research areas for Medicare and Medicaid, yet it does not identify how much is Medicare and how much is Medicaid.

Please distribute your research money between Medicare and Medicaid funds by area.

Answer: The estimated distribution for Medicare and Medicaid funds by major area of research for 1979 and 1980 is supplied for the record.

Distribution on Research Funds by Area between Medicaid and Medicare (amounts in millions)

Major Area	1979 Medicaid	1979 Medicare	1979 Total	1980 Medicaid	1980 Medicare	1980 Total
1. Hospital Costs	$2.2	$4.8	$7.0	$2.1	$3.9	$6.0
2. Physician Reimbursement	1.1	2.4	3.5	1.0	2.1	3.1
3. Long Term Care	5.7	0.3	6.0	20.7	0.3	21.0
4. Health Systems Organization	1.9	2.1	4.0	1.8	2.2	4.0
5. Quality and Effectiveness	0.7	0.6	1.3	1.0	1.1	2.1
6. Integrated Data Systems	0.8	1.7	2.5	1.5	3.5	5.0
7. Fraud and Abuse	2.0	---	2.0	2.0	---	2.0
8. Program Evaluation	1.5	---	1.5	2.1	---	2.1
9. Beneficiary Impact and Related Areas .	1.6	1.5	3.1	2.6	2.9	5.5
10. Industrial Organization and Reimbursement	0.2	0.3	0.5	0.2	0.3	0.5
Total	$17.7	$13.7	$31.4	$35.0	$16.3	$51.3

The distribution is based on the relative dollar value of benefits paid among the various types of services or providers by area between Medicare and Medicaid. Funding for an individual project witnin a program area will depend on the nature of the research being performed, i.e., whether it relates to Medicare or Medicaid beneficiaries. It is not unlikely that a particular project might be funded with all trust or general funds, or a combination of the two that would be at variance with the overall ratio for all projects in that area.

Questions Submitted by Senator Schweiker

SINGLE CONTRACTOR

Question: I understand that an internal HEW study recommended last October, joint administration of Medicare and Medicaid under a single contractor. Is that correct? Have you made any decision as to your position on this recommendation? Do you have any estimates of the administrative cost savings which would result from such a consolidation?

Answer: An internal Steering Group submitted a report on October 31, 1978, recommending that HCFA experiment with joint administration of Medicare/Medicaid through a common contractor to determine whether or not there would be any benefits which might be realized. Staff work done in connection with the report indicated there may be some long-range cost savings through integration of the pro-

grams. However, it was also estimated that for the first few years of integration, there would be additional cost as systems are revised to make the programs compatible. None of the estimates were based on hard data and for that reason it was recommended that experiments be conducted to test the feasibility and benefits of integration. As of this date, there have been no experiments in this area, although we are doing additional staff work and planning to test the benefits of consolidation.

REGULATIONS REVIEW

Question: What progress can you report so far?

Answer: We have established an Office of Health Regulation which entered its first staff on duty March 19, 1979. The Office expects to start the review of regulations affecting health care institutions by the end of April 1979, after certain essential preliminary work is completed.

Question: What do you hope to achieve by this review?

Answer: We expect to reduce the burden of regulation on health care institutions by eliminating duplication of reporting and other unneeded management activities and by insuring that all the regulations affecting similar activities are consistent. We intend to insure that the benefits received by patients are provided in the most cost effective manner.

Question: What do you mean by your statement that regulations must be reformed so that they channel funds more appropriately?

Answer: Regulations can be written so that they encourage economically efficient or inefficient behavior by providers. We will insure that regulations are written so that we pay for only the most efficient provision of service while maintaining the benefits to the patients.

Question: Is it true that on request HCFA officials have refused to visit clinics in the North Carolina network in February?

Answer: A visit to North Carolina was planned for February 14. Some of our staff could not attend and the visit was postponed. There have, however, been numerous meetings and visits conducted in the past. HCFA has developed good communications with clinic representatives and has met with these representatives on many occasions. We expect to continue our dialogue in the future.

UNIFORM REPORTING REQUIREMENTS FOR HOSPITALS

Question: You are saying that you estimate it will cost an average of $8,000 per hospital to convert to the uniform reporting requirements proposed in January. You also indicate it could cost a lot more, depending on whether or not a facility "chooses" to switch to a uniform accounting system to accommodate the new

reporting requirements. Since a number of hospital administrators claim they will have to implement a uniform accounting system to effectively comply with the new reporting plan, do you intend to take into account the estimates the American Hospital Association is gathering from its 6,000 member facilities as to how much it will cost to convert? If you maintain that uniform accounting is not necessary to comply with uniform reporting, are you doing any studies of the relative costs for hospitals to maintain two systems and transcribe the data each year to the uniform reports versus making a one-time conversion to a standard accounting and reporting system? I'd appreciate your supplying the committee some information in this regard.

Answer: Uniform reporting systems virtually identical to the System for Hospital Uniform Reporting, or SHUR, are in place in over 20 percent of the nation's beds--California, Washington, Arizona and New York. Our existing conversion cost estimates are based on experience in these States. Recently, the Health Care Financing Administration has in conjunction with the American Hospital Association designed an empirical study of the cost of implementing SHUR. This empirical study developed jointly by the American Hospital Association and HCFA has been implemented under a contract with an accounting firm. This accounting firm will be entering a sample of hospitals jointly chosen by HCFA and the American Hospital Association. This precise empirical assessment of the implementation cost should provide accurate estimates of the conversion costs. We will also consider any information that the American Hospital Association might make available.

We believe the SHUR system will ultimately pay its own way with the savings it will produce in the Medicare and Medicaid programs--programs that will spend more than $40 billion this year. SHUR will identify fraud, abuse and waste and permit us to eliminate payments for them. This will not only save the taxpayers' money, but will also help curb hospital costs--costs that have doubled in the past five years.

It is important to note that SHUR does not require hospitals to adopt a uniform accounting system. SHUR does, however, as the law specifies, require that reconciliation of internal accounting records be completed in such a fashion that the SHUR reports develop truly comparable data. Hospitals do have an option. Institutions are free to adopt the chart of accounts contained in SHUR or cross walk information from their current chart of accounts to the SHUR reports. The HCFA study will assess the cost of meeting the SHUR reporting requirements under either option. That is, either cross walking current accounting information to the new reporting forms or optionally choosing to implement the accounting system contained in the SHUR manual.

The report on the implementation cost under both options is to be available April 16. I would be pleased to supply it for the record at that time.

RURAL HEALTH

Question: Is it true that the Bureau of Health Manpower is making training grants for nurse practitioners and physician

assistant training to states in which one or the other is not legally entitled to practice? If so, what is the justification for these grants?

Answer: There are no training grants issued for these purposes. Nurse practitioners are legally entitled to practice in all states. Physician assistants are legally entitled to practice in all states except New Jersey.

Question: What is the status of the preventive health care reimbursement demonstration authorized in the legislative history of the Rural Health Clinics Act, P.L. 95-210?

Answer: A number of new research and demonstration activities were inaugurated late in the last Congress--among which is the preventative health care demonstration. Our capability to perform all such activities is, of course, limited by availability of resources and we have had to prioritize these new and existing requirements within these resources. In this process, unfortunately we have had to delay implementation of the preventative health care demonstration.

Question: I understand that 15 clinics have dropped out of the Rural Health Clinics Medicare/Medicaid program. Is it true that the reason was the amount of paperwork involved?

Answer: Clinics have dropped out of the program for a variety of reasons. Somce clinics did not fully understand the mechanism for reimbursing rural health clinics and after discussion with our intermediaries they determined that they wished to continue to receive payment for Medicare and Medicaid on the usual basis.

While there is some paperwork involved in the program we have tried to keep the process as simple as possible. We believe that both the certification process and the payment process for Medicare are working smoothly.

Question: What is the lead DHEW/HCFA agency for this program and who is responsible for all of the paperwork? Did an accountant design the forms involved?

Answer: The Health Standards and Quality Bureau is responsible for the certification process and the Medicare Bureau is responsible for Medicare reimbursement. Each of these Bureaus designed the applications and forms being used. A staff accountant participated in the development of the Medicare forms.

Question: Is it true that the Health Care Financing Administration has no one with line authority designated as responsible for the implementation of P.L. 95-210?

Is it true that the responsibility is there fore diffuse and often not coordinated?

Answer: Responsibility for implementing the Rural Health Clinic Act is vested in the operating bureaus of HCFA. A project manager was appointed by the Administrator to coordinate implementation. We have acted in a timely and coordinated fashion since the enactment.

SUBCOMMITTEE RECESS

Senator CHILES. The subcommittee will stand in recess.

[Whereupon, at 12:10, Thursday, March 8, the subcommittee was recessed to reconvene at the call of the Chair.]

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